Responses to USEPA Comments
Baseline Ecological Risk Assessment
Newark Bay Study Area
Newark Bay, New Jersey

Comment No.	Section	Page	USEPA Comment on April 2019 Draft BERA (July 11, 2019)	GSH Response	USEPA Clarification Dated January 6, 2020	USEPA Back-Check of Response to Nov 2019 Draft BERA (February 28, 2020)	GSH Response to Clarification/Backcheck
1	General	NA	Please define concepts and terminology when first introduced and use consistently throughout the document. Also, please conduct a thorough editorial review of the revised Baseline Ecological Risk Assessment (BERA) as several misspellings (including Latin binomials) were noted, particularly in Appendix D.	This comment has been addressed. An editorial review has been conducted on the main text and appendices, and consistency in concepts, definitions and language has been updated as needed and in response to other more specific comments.		Response acceptable; however, please consider this comment during preparation of next version as errors were still noted (examples include bottlenose dolphin and menhaden) in the revised draft.	All scientific names in the BERA were reviewed and revised as necessary.
2	General	NA	Please include a footnote using the NJDEP disclaimer language below where the Lower Passaic River Study Area (LPRSA) Toxicity Reference Values (TRVs) are first mentioned in the document: It is the New Jersey Department of Environmental Protection's (NJDEP's) position that a single toxicity reference value (TRV) set (No Observable Adverse Effect Level [NOAEL] and Lowest Observable Adverse Effect Level [LOAEL]) that evaluates the more sensitive species and endpoints to characterize risk to invertebrates, fish, birds and wildlife should be selected in a Baseline Ecological Risk Assessment (BERA), not two sets of TRVs as presented in this document. The NJDEP's Ecological Evaluation Technical Guidance, August 2018, does not advocate the use of more than one set of TRVs for individual contaminant-receptor pairs. It is the NJDEP's position that use of one conservative TRV set derived for sensitive receptors and sensitive endpoints most clearly demonstrates the degree of risk for individual contaminant-receptor pairs and ensures protection of threatened, endangered and species of special concern.	This language has been inserted as a footnote in Section 3.5.2 where TRVs are first discussed.		Response acceptable.	N/A

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3	General	NA	All NOAEL- and LOAEL-based Hazard Quotients (HQs) ≥ 1 must be carried through the entire analysis and used to draw conclusions about the range of potential ecological risks.	As discussed and agreed upon in a conference call with the USEPA team on September 23, 2019, all NOAEL- and LOAEL-based HQs are presented in the Draft BERA for each receptor group and exposure pathway evaluated. The discussion in each section is primarily focused on the LOAEL-based HQs, as those are used to identify the preliminary chemicals of concern (COCs). This approach is entirely consistent with the Final USEPA-approved BERA for the LPRSA that was released in June 2019. A primary focus of the NBSA BERA has been to maintain consistency with the approach used for the LPRSA.		The process of identifying preliminary COCs is not consistent with that used in the LPR OU4 BERA. LOAEL-based HQs, rather than NOAEL values, were used to identify preliminary COCs in both the LPR OU4 and NBSA BERAs. A key difference between the two analyses is that only in the LPR BERA were FFS LOAEL HQs >= 1 considered a sufficient basis for selecting preliminary COCs. In contrast, in the Revised NBSA BERA, a TRV reliability scoring process was used and exceedance of the NBSA, but not the LPR FFS TRVs, was a necessary criterion for identifying preliminary COCs. See Comment #175, which concerns potential evaluation bias in interpreting LOEs that is used to support risk classification and Comment #195. Based on the information provided in the revised BERA (Tables 7-24, 8-15, and 9-8), preliminary COCs should be identified for fish (mummichog/killifish, American eel, flounder and white perch), birds (sandpiper, heron, cormorant and scaup), and mammals (otter). Note that preliminary COCs should be identified if any LOAEL HQ >=1 in any zone within the Bay (even if the result for the overall Bay does not); similarly, preliminary COCs should be identified if sensitivity analysis scenarios or alternative SSD 5th percentile estimates (based on different distribution assumptions in the OU4 BERA) result in LOAEL HQ>=1 (see Table 1).	The NBSA BERA has been updated to align the NBSA TRVs with the LPRSA TRVs, with the exception of the few NBSA COPECs that were not assessed in the LPRSA BERA. The NBSA TRVs and LPR FFS TRVs are now treated equally as a range of TRV values in the NBSA and for the purpose of establishing preliminary COCs. All LOAEL HQs ≥ 1 based on either NBSA or LPR FFS TRVs, and for all risk assessment zones and sensitivity analysis scenarios, are now included as preliminary COCs for each receptor in the risk conclusions of Sections 6 (benthic invertebrates), 7 (fish), 8 (birds), and 9 (mammals). The selection of the final recommended COCs from this list, based on the lines of evidence are also presented in each section, and summarized in Section 11. The recommendation of final COCs, based on weight-of-evidence considerations, is consistent with both the LPRSA (OU4) BERA and the OU2 BERA. Summary tables of HQ ranges consistent with the example "Table 1" provided by the USEPA in the Backcheck Response to Comments document dated 02/28/2020 are now included in Sections 6 through 9 of the NBSA BERA. The example uncertainties summaries in the USEPA's example Table 1 are contained in the weight-of-evidence tables in each of these sections.
4	General	NA	Please explore whether any more definitive conclusions can be drawn from the available historical ichthyoplankton data as a qualitative but standalone Line of Evidence (LOE). For instance, are there any species or life stages that one would expect to see and are missing? Are there any useful datasets available from other mid-Atlantic estuaries (e.g., Chesapeake Bay) that could provide insights into typical demographic transition probabilities for comparison	This analysis has been included in the new fish community LOE that has been added as Section 7.1 in the revised BERA. Available data from ichthyoplankton, juvenile, and adult fish surveys conducted concurrently in the NBSA and other areas of the NY/NJ Harbor Estuary as presented in USACE reports cited in the BERA are characterized and compared, and these data are put into perspective to the extent possible relative to what is expected for mid-Atlantic estuaries per the USACE's analyses and scientific literature.	On the July 29th call, GSH agreed to include the historical ichthyoplankton data from the USACE fish surveys in the revised BERA and to discuss the uncertainties associated with this LOE for the fish assessment endpoint.	Response acceptable. The fish community LOE, including a thorough summary of the available fish community data for Newark Bay, is an important addition to the analysis presented in the draft; however, please see Comment #43 regarding interpretation of this LOE.	We agree with this comment. See response to Comment 43.

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			to the NBSA data? Also, please consider the actual collection data (species/life stage and time of year occurrence) in the context of life history information that is well-documented in Appendix B. Please update appropriate sections of the BERA as appropriate.				
5	General	NA	The BERA should include evaluation of both current and future (absent remedial effort) conditions in NBSA. Please acknowledge both exposure settings and either reference appropriate discussion in the Remedial Investigation (RI) Report regarding the unlikeliness of potential future exposure to deeper sediment [below the Biologically Active Zone (BAZ)] and summarize the technical rationale or include an assessment of subsurface sediment chemistry in the BERA.	There are no expected changes in the ecosystem of the NBSA for the foreseeable future that would alter exposure conditions for the species evaluated in this BERA. A brief discussion has been excerpted from the RI and included in Section 2.1.3 regarding sediment stability, improving sediment chemistry conditions over the past decades (and likely into the future), and the unlikelihood of exposures of benthic invertebrates to sediments below the BAZ.		Response acceptable.	N/A
6	General	NA	Characterizing risk as "unacceptable" implies a risk management perspective that is not appropriate for the BERA. Also, in consideration of Comment No. 3, please revise the risk classification assignments presented throughout the document.	See response to General Comment 3. This comment is not consistent with language used throughout the Final LPR BERA, in which the term "unacceptable risk" is applied as defined in that document (to describe risk conclusions based on a specific set of HQs and LOE). It is important to maintain this consistency in both documents, and no change is proposed to the NBSA BERA in response to this comment.		Response acceptable.	N/A
7	General	NA	The toxicological profiles (Appendix D) present a discussion of uncertainties that is biased against the Lower Passaic River (LPR) Focused Feasibility Study (FFS) values and uncertainties associated with the CPG values and those developed specifically to support the BERA are rarely discussed. Please review and update the information to provide a balanced review of the studies with consideration to all relevant uncertainties. As indicated in Comment No. 3, the goal of the two-tiered TRV approach is not necessarily	Appendix D has been updated to address this comment.		This response will be evaluated following revisions to Appendix D based on the supplemental comments.	See response to supplemental Appendix D comments 187 - 253 below.

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			to advocate for one or the other, but rather to highlight the uncertainties associated with each so that EPA can make informed decisions regarding how best to abate ecological risks.				
8	General	NA	Consistent with the 17-mile LPR BERA, final chemicals of concern (COCs) will be determined in consultation with EPA. In addition, please include all receptor-chemical of potential ecological concern (COPEC) combinations with NOAEL- or LOAEL-based HQs >1 inclusive of both Newark Bay Study Area (NBSA) and LPRSA FFS TRVs as "potential COCs" and those with LOAEL-based HQs > 1 as "risk drivers" unless a credible rationale can be provided to the contrary (e.g., lack of bioavailability). Finally, all COPEC-receptor pairs where "unacceptable risk is uncertain" should also be carried forward for additional evaluation in the NBSA Feasibility Study (FS).	See response to General Comment 3. The designation of "potential COCs" as specified in this comment is not consistent with the approach used in the Final LPRSA BERA. Both NOAEL- and LOAEL-based HQs are provided and summarized in both the Final LPRSA and Draft NBSA BERA. LOAEL-based HQs>1 are used to identify "preliminary COCs" in both the Final LPRSA and Draft NBSA BERA. A discussion of these preliminary COCs as "risk drivers" is then presented in the conclusions/summary sections of each BERA. It is important to maintain this consistency in both documents.		USEPA agrees that consistency in how preliminary COCs are identified in the two BERAs is important and the focus on LOAEL HQs in this process is acceptable; however, see Comment #3.	See response to Comment 3.
9	General	NA	There is some confusion about exposure areas, geomorphic areas, and ecological habitats as presented in Table 2-2 and elsewhere in the text. For example, are "intertidal areas" equivalent to "mudflats" and how does the industrial waterfront area correspond to the shoreline exposure habitat? Please ensure that these are clearly defined and referenced consistently throughout the document. Fish and wildlife foraging assumptions in the different habitats are also sometimes confusing (e.g., muskrat use of shoreline and assessment zones). Finally, it was not clear which specific samples were assigned to each habitat type, so please make foraging assumptions explicit in the exposure section of each AE. See specific comments below.	New tables in Section 4 (Tables 4-10 and 4-11) have been added that list the assigned assessment zone for each sediment and tissue sample. A new Figure 4-4 has also been added that shows the assigned assessment zones of each sediment sample in the NBSA. Additional clarifying text has been added to Sections 4 and 7 through 9 as well for the exposure assessments for specific receptor groups (i.e., fish, birds, and mammals, respectively). The text in Section 2.1.4 has been clarified to explain that Table 2-2 is showing the geomorphic areas of the NBSA and that the subtidal flats are the main habitat for aquatic organisms.		The additional figure and tables are helpful. Table 4-11 includes laboratory-exposed invertebrates, which is helpful, but please add a footnote to distinguish the other samples. What are the proposed subunit codes (a, b, c)? Please add a footnote. What are the USEPA subunits in Figure 4-3 and why are they identified in the figure? In Figure 4-4, what is the distinction between the "regularly-dredged deep water channel assessment zones and samples (red)? Please ensure that assumptions of ecological exposure to the navigation channels that are routinely maintained and those that are not (north of the Port Newark Channel) is made clear.	A footnote was added to Table 4-11 to indicate that the polychaete samples were laboratory-exposed tissue samples, not tissue samples collected from the Bay. Figure 4-3 shows the sampling locations from the Phase III sediment sampling program. For the Phase III program, Newark Bay was divided into six subunits proposed by the USEPA (USEPA 2015). For further information on the Phase III sampling subunits, see the Phase III Sediment Investigation Field Report, Revision 1 (GSH 2017). Figure 4-4 was revised to show the difference between the unmaintained and undredged navigation channel north of Port Newark Channel and the regularly dredged navigation channels below and including Port Newark Channel. The red circles indicate samples collected from the regularly dredged navigation channels.

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10	1.1	2	1st – 2nd paragraphs. While references to USACE documents are acceptable, the BERA would benefit from incorporation of site-specific data. For example, on page 2, in paragraph 1, the BERA references USACE 2007b for salinity values in the bay. Please add that the salinity range of 0.5-30 ppt reported by the USACE is consistent with the water quality data collected during the Physical Water Column Monitoring (PWCM) program. On page 2, in paragraph 2, the BERA references USACE 1997 for grain size distribution data. Please verify that the Phase I/II grain size data are consistent with the USACE dataset and add a reference to these data.	Section 1.1 has been updated to include and primarily reference site-specific (i.e., RI and PWCM program) salinity and grain size data.		Response acceptable.	N/A
11	2.1.1	6	2nd paragraph. The BERA states that "Commercial use of local waterways expanded between 1920 and 1950, driven by demands associated with World Wars I and II (Squires 1981)." The chronology in this sentence doesn't appear correct, since World War I ended on November 11, 1918; therefore, changes in commercial use after 1920 would likely be attributed to a different driver. Please check the reference and revise the sentence accordingly.	This comment has been addressed.		Response acceptable.	N/A
12	2.1.1	7	3rd paragraph. The BERA states that "The depth and width of the navigational channels have grown continually since the early 1900s (USACE 2006a), although channels in some adjacent water bodies (e.g., the Lower Passaic River [LPR] and Hackensack River) are no longer maintained to their previously authorized depths." Please add a statement that the navigation channel in the LPR above RM1.7 has been deauthorized.	This comment has been addressed.		Response acceptable.	N/A

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13	2.1.2	7	Numbered list and paragraph below list. The BERA states that the NBSA shoreline consists of 40% bulkhead, 10% mixed industrial, 30% riprap, and 20% vegetation. It then states that human uses of the NBSA shoreline consist of 19% disturbed uplands, 35% industrial/commercial, 13% recreational or habitat/recreational, and 8% residential shoreline uses. Please reconcile this information and confirm that it agrees with descriptions in the approved Conceptual Site Model (CSM) document.	The text has been revised and is in agreement with the approved Conceptual Site Model. The term "mixed industrial" was corrected to "mixed intertidal."		Please conduct a global search/replace for "mixed industrial" and revise the document as necessary (e.g., bullet 2 in Section 2.1.2). The percentages in the new text do not add up to 100%.	Mixed industrial was revised to mixed intertidal in Section 2.1.2. The numbered bullets on approximate shoreline land use add up to 100% (40%, 10%, 30%, 20%). The bulleted list of approximate upland land use add up to 100% (20%, 25%, 35%, 10%, 10%).
14	2.1.2	7	In Bullet 4, the BERA states that approximately 20% of the NBSA shoreline is classified as vegetated (greater than 50% emergent vegetation). This statement appears to conflict with the sentence below the bullets on Page 7 stating that "Approximately 25% of the shoreline is classified as habitat." Is "potential ecological" habitat implied in the second statement? Please discuss the relationship between these two shoreline categories in the text.	See response to Comment 13. The text has been revised and is in agreement with the approved Conceptual Site Model. The first categorization is describing shoreline types (e.g., bulkhead, riprap, etc.) The second categorization refers to upland characterization adjacent to the shoreline. The statement "Approximately 25% of the shoreline is classified as habitat" has been deleted.		Please refer to Comment #13. Also, based on GSH's response, please revise new text to state: "Based on a reconnaissance survey (Tierra 2015a), five human use categories were established and described as follows along with the percentage of UPLAND CHARACTERIZATION ADJACENT TO THE shoreline where each was observed".	The text was revised as requested and is consistent with Comment 13.
15	2.1.3	8	Last sentence. Please caveat NBSA documents submitted by Tierra Solutions, Inc. or Glenn Springs Holdings that have not been approved by EPA, including but not limited to the "Report on Investigation of Sources of Pollutants and Contaminants (Tierra 2006)."	This comment has been addressed.		Response acceptable.	N/A
16	Table 2-2	9	See Comment No. 9. Please clarify whether there are any differences between the "subtidal flats" and "historically disturbed subtidal flats" areas from an ecological exposure/habitat perspective. In addition, please explain why the CDF is considered an "area of importance" and whether ecological habitat use in this area is distinct from other identified geomorphic areas. Also note	There are no differences between subtidal flats and historically disturbed subtidal flats from a habitat perspective. This has been clarified in the text. The CDF is not an area of ecological importance and the statement has been deleted. See also responses to Comments 9 and 50.		Response acceptable.	N/A

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			Comment No. 50 regarding the zone assignment for the CDF.				
17	2.1.4.2	12	1st paragraph. The BERA states that "Nearly half of the NBSA bottom area is composed of shallow subtidal flats (< 8 ft. average depth), and more than 40% is maintained navigation channels and their transitional side slopes (Table 2-2)." Please revise this sentence for further clarity by adding the phrase "an additional" prior to the phrase "...40% is maintained navigation channels..."	This comment has been addressed.		Response acceptable.	N/A
18	2.1.4.2	13	1st sentence. Please clarify what is meant by "continuous dredging operations" in the navigational channels. Is the time between dredging events considered too short to allow establishment of stable macroinvertebrate communities or are other factors such as ongoing sloughing and ship activity the primary reasons why this habitat is considered relatively unstable?	The word continuous has been changed to "periodic." The dredging to bedrock in these channels and continuous disturbance by ship traffic, presumably to the authorized depths (since deepening to allow large drafts for ships is the rationale for the regular dredging operations conducted by the USACE), are the reasons why these habitats are not likely stable.		Response acceptable; however, the macroinvertebrate community reestablishment timescale (probably 2-3 years for Stage III) relative to dredging and potential consequences to ecosystem functioning should be discussed. While acknowledging that the navigational channels provide both habitat and forage, the revised text still appears to diminish the importance of a habitat that represents 40% of the Bay. As a result, the exclusion of this area from the quantitative analysis represents a BERA uncertainty that should be discussed further. This discussion should include a comparison of the chemistry for the 10 composite sediment samples to the other areas (this summary is missing from Table C-1 and should be added).	The sediment chemistry of the 10 composite samples from the regularly dredged navigation channels was added to Table 4-12. These 10 composite samples are included in the NBSA-wide dataset used for risk analyses as discussed in Section 4.4.1.

Additional text discussing the habitat provided in the regularly dredged deep water channels, and the potential impact of regular dredging on the benthic community has been added to Section 2.1.4.2.

A summary of general comparison between regularly dredged deep water channel sediment chemistry data and other areas within the NBSA was added to Section 4.4.1.

Additional discussion of the regularly dredged deep water channels has been added to the uncertainty discussion in Section 6.4. |
| 19 | 2.1.4.2/ Table 2-5 | 13 | How were the 21 species included in Table 2-5 selected? Additional fish species were caught and identified during the RI. Please clarify the basis for the species list and consider including all fish species observed. | Table 2-5 and the text have been updated. These are the 19 species that NOAA/NMFS lists as having essential fish habitat (EFH) in the NY/NJ Harbor Estuary, including Newark Bay. | | Response acceptable. | N/A |
| 20 | 2.1.4.2 | 13 | Table 2.5, Essential Fish Habitat (EFH), and the text reference USACE (2015), which is listed as the Migratory Finfish Summary Report; rather than the USACE (2013) EFH report available on | See response to Comment 19 regarding EFH and the number of species. The comment regarding the correct USACE citation has been addressed. There have been no changes in the EFH species in | | Response acceptable. | N/A |

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			the USACE New York District website, which would be more appropriate as there is no EFH table in USACE (2015). More globally, suggest updating the EFH table with current data from the National Marine Fisheries Service website, as species/life stages may have changed and would be more specific to Newark Bay (as the USACE EFH table was for all of NY Harbor). Also, please correct the inconsistency between Table 2.5, which lists 20 EFH species and the text, which states 21 species.	Newark Bay in recent years. An updated 2019 EFH assessment was conducted and the reference has been modified accordingly.			
21	2.3.1	15	2nd paragraph. The information presented in Figures 2-3 and 2-4, along with the summary of REMAP program data in Table 2-7, suggests that benthic conditions in the bay have improved over the last 3 decades. Please add the Benthic Invertebrate Community (BIC) data collected in 2015 to Table 2-7 to benchmark historical trends and support conclusions that the 2013 REMAP results were anomalous. The trends in the benthic community data (Benthic Index of Biotic Integrity [B-IBI] and individual BIC metrics) are generally consistent with available laboratory toxicity test results collected during this period, although use of a different test species in 2015 contributes uncertainty. The conclusion that sediment chemistry is a likely stressor to the benthic community should be enhanced by demonstrating that trends in sediment chemistry are consistent with the biological response metrics. Recognizing that there are some inconsistencies between the RI and historical chemistry datasets, please consider including a summary of historical trends in sediment chemistry to this analysis. Also, please consider whether additional multivariate analysis would be helpful to better	The BIC data from 2015 have been added to Table 2-7 as requested. An evaluation of the historical data has been added to the BERA in Appendix A (Section 3.4). Major COCs (e.g., dioxins, PCBs) were not consistently measured in the historical data sets therefore multivariate analyses were not attempted. However a Spearman correlation analysis of the historical sediment data versus toxicity and BIC metrics has been added to the BERA in Appendix A (Table A-32). A discussion of the historical decline in the incidence of toxicity has been added to Appendix A (Section 3.4; Figure A-36) and also summarized in Section 2.3.1.		Response acceptable; however, please indicate whether the level of taxonomic identification is similar within higher taxonomic groups between the REMAP and 2015 benthic community datasets. If differences are identified please provide a discussion on potential impacts on the metric comparisons.	The following text has been added to Section 2.3.1: "In each program, specimens were identified to the lowest practicable level, usually genus and species (Tierra 2015b; USEPA 2003a)."

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			understand the importance of this stressor category on the benthic community.				
22	2.3.2	17	2nd paragraph. Are crab carapace and softshell clam length data available for other comparable estuaries that could be summarized here to help interpret the information provided?	Tables have been added to Section 2.3.2 that summarize the size ranges of softshell clam lengths and blue crab carapace widths from other estuaries. Appropriate discussion has also been added to the text.		Response acceptable; however, please discuss alternative interpretations of the small range of clam widths. Why were there few if any normally-sized, adult-age clams collected in the sampling program? It can't be ruled out that the Bay fauna includes undersized adults and if so possible explanations (habitat, competition, chemical stressors) should be discussed. Another consideration is that the lipid fraction of some clams appears to be low relative to other mid-Atlantic clam populations (see Comment #69) and this could be a health indicator associated with NBSA stressors.	Additional text has been added to Section 2.3.2 regarding the potential reasons for the differences in softshell clam widths from the NBSA compared to other mid-Atlantic locations. The lipid issue is discussed pursuant to Comment 69 in Section 6 of the BERA.
23	2.4	17	2nd paragraph. See Comment No. 20 regarding EFH and the reference to USACE (2015).	See response to Comment 20. The reference has been corrected.		Response acceptable.	N/A
24	2.4	17	In addition to the 21 species for which the NBSA is designated EFH and the two Federally-listed species, this section should include discussion of the NOAA Species of Concern (SOC) known to utilize the NBSA - alewife, blueback herring, and rainbow smelt. SOCs are species for which NOAA's National Marine Fisheries Service has concerns regarding danger of extinction or risk of becoming endangered but for which insufficient information is available to indicate a need to list. SOC can also include species that have undergone a status review which resulted in a "listing not warranted" determination but where significant concerns or uncertainties remain.	A discussion of SOCs has been added to this section.		Response acceptable.	N/A
25	2.4	17	Last paragraph. There are other important forage fish in the NBSA that should also be discussed here such as bay anchovy, Atlantic silverside, and river herring (alewife/blueback herring).	A discussion of other important forage fish species has been added to this section.		Response acceptable.	N/A

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26	2.4.1	18	1st paragraph. What are the habitat conditions referenced in the second to last sentence and what is the significance if any of the white perch exception? What is known about the spatial and temporal variability in Dissolved Oxygen (DO) conditions throughout the Bay and the potential importance of this stressor in structuring the fish community?	The language "the extant range of habitat conditions" referenced in the comment has been replaced with "throughout Newark Bay." Additional discussion regarding NOAA's findings on DO in this particular historical study are summarized. It is also acknowledged that it is unknown if such low DO conditions still occur in the Bay, given improvements in water quality conditions in the last 2+ decades.		The revised text still appears to infer that the low DO was an important determinant of the spatial distribution of white perch. Is this the intent (if so more discussion should be provided) or can this just be removed to reduce confusion?	The sentence on distribution of white perch and DO in the Bay was removed.
27	2.4.1	18	3rd paragraph. USACE (2015) summarized the results of the 2006 and 2011-2013 mid-water trawl surveys, not the Aquatic Biological Survey (ABS) data. The ABS data set was summarized in a few reports available on the USACE NYD website, primarily "Demersal Fish Assemblages of NY/NJ Harbor and Near-Shore Fish Communities of NY Bight." The two studies seem to be mis-referenced in the text of the BERA; please correct the text.	The references have been corrected.		Response acceptable.	N/A
28	2.4.1	19	2nd paragraph/first line. Please correct to "…during nine years of sampling".	The text has been corrected.		Response acceptable.	N/A
29	2.4.1	19	4th paragraph. Please add that the 1999 to 2006 USACE ichthyoplankton data was collected on a seasonal basis (generally from January to June), so some species/early life stages may be under represented in the data.	The suggested text has been added.		Response acceptable.	N/A
30	2.4.1	19	4th paragraph. Please delete the text "…including eggs and larvae from **one** unidentified species…" as unidentified organisms could not be identified to the species level and therefore could include more than one species.	The text has been deleted as requested.		Response acceptable.	N/A
31	2.4.1	19	4th paragraph. Suggest deleting the sentence that begins with "it is unclear why the counts of juveniles are much lower…." As described in the sampling methods sections of these reports, the ichthyoplankton survey design/gear selection was intended to target eggs and larvae. Juveniles were only occasionally collected as by-catch and	The sentence has been deleted.		Response acceptable.	N/A

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			were targeted separately in the bottom trawl survey.				
32	2.4.1	19	4th paragraph. Fish are known to be particularly sensitive to dioxin/furan and coplanar PCBs during early life stage exposures and excess mortality due to contaminant exposure should considered as a potential factor associated with unexpected observations in the historical dataset. See Comment No. 4.	The USACE ABS surveys did not target the juvenile life stage, therefore juvenile counts from these surveys are expected to be under-counted. Juveniles were targeted in the demersal fish surveys conducted by the USACE during those same time periods.		Response acceptable. The fish community LOE, including a thorough summary of the available fish community data for Newark Bay, is an important addition to the analysis presented in the draft; however, please see Comment #43 regarding interpretation of this LOE (and others) in the WOE integration process.	See response to Comment 43.
33	2.4.2	20	Note that horseshoe crabs are not true crabs (i.e., decapod crustaceans). Please clarify text.	The text has been clarified as requested.		Please correct the revised text as horseshoe crabs are chelicerate arthropods, not decapod crustaceans.	This correction has been made.
34	2.5	21	To the extent possible, please structure the discussion of bird fauna around various trophic levels to help establish the linkage between potential receptors and assessment endpoints. Same comment for Section 2.6.	This comment has been addressed in Sections 2.5 and 2.6.		Response acceptable.	N/A
35	2.6	22	Please confirm that the river otter is a "common" inhabitant in the region.	This comment has been addressed. The word "common" was replaced by "potential" as the reports of river otter occurrence in the Bay are anecdotal, but habitat is present to support their presence.		Response acceptable.	N/A
36	2.6	22	Please delete the first paragraph in Section 2.6, as the information is duplicated in the 3 paragraphs that follow it.	The paragraph has been deleted.		Response acceptable.	N/A
37	2.6	23	This section should include discussion of harbor seal and grey seal, two marine mammals likely to be present and feeding in, or proximate to, the NBSA. In addition, pods of dolphins have been observed just outside the NBSA and discussion of these mammals included in this section.	A discussion of the harbor seal, grey seal, and whales and dolphins has been added to the text.		Response acceptable.	N/A
38	2.8	23	Although not currently federal- or state-listed, the northern diamondback terrapin (*Malaclemys terrapin terrapin*) has been under review for possible listing (see 2016 Species Status Review of Amphibian and Reptiles,	Text has been added discussing the potential status of the diamondback terrapin.		Response acceptable.	N/A

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			http://www.nj.gov/dep/fgw/ensp/pdf/ herp_status_rprt.pdf) and is known to occur in the Hackensack River watershed. In addition to potential chemical stressors such as PCBs, population stability is under threat from habitat loss, road kills, and crabbing by-catch factors. Please indicate the potential status consideration in Section 2.8.				
39	3.1	26	1st paragraph, last sentence. EPA Data Quality Objectives (DQO) guidance recommends establishing the null hypothesis based on the assumption that a site is contaminated relative to background or reference conditions. In contrast, the formulation used in the text is more appropriate for assessing conditions following remedial action. This has potential significance due to the relative acceptable error rates associated with Type I and II errors. Please clarify and evaluate whether there are impacts on any of the hypothesis testing conducted in support of the BERA (e.g., SQT analysis).	All hypothesis tests comparing site metrics to reference metrics were conducted as one-sided tests where the alternative hypothesis is that the site metric demonstrates degradation. This is consistent with the formulation of hypothesis tests described in EPA guidance (USEPA 2006a, 2006b). The text has been revised to state this.		USEPA disagrees with the GSH response. Per the cited reference (USEPA 2006a) "It is important to take care in defining the null and alternative hypotheses because the null hypothesis will be considered true unless the data demonstratively shows proof for the alternative" (page 16). At this phase in the NBSA RI/FS process, the consequences of inappropriately concluding that ecological risk doesn't exist (Type I error) outweighs the alternative of incorrectly concluding that it does (Type II error). "It is often useful to choose the null and alternative hypotheses in light of the consequences of making an incorrect determination between them. The true condition that occurs with the more severe decision error is often defined as the null hypothesis thus making it hard to make this kind of decision error. The statistical hypothesis framework would rather allow a false acceptance than a false rejection." The potential consequences on the conclusions drawn from the statistical analyses should be discussed.	The following text has been added to Section 3.1: "A potential consequence of hypothesis testing is a Type II error, (i.e., accepting the null hypothesis, when it is, in fact, false). Adequate sample size is the best way to avoid such an error." It is important to note that in the BERA, hypothesis testing was used to compare benthic metrics in the NBSA to those of Jamaica Bay (JB). All hypothesis tests comparing NBSA metrics to JB metrics were conducted as one-sided tests where the alternative hypothesis is that the NBSA metric demonstrates degradation. This method and formulation is both appropriate and consistent with USEPA statistical guidance (USEPA 2006b). Further, it is consistent with the formulation of hypothesis tests used in the SQT assessment presented in the Final BERA for the LPRSA (Windward 2019). If the null hypothesis were set up such that NBSA benthic metrics are considered degraded compared to JB as the comment seems to suggest, it would be impossible to prove otherwise if the two sites had equivalent benthic invertebrate communities. The only way to prove otherwise is if the NBSA benthic metrics were significantly greater than the JB metrics. For some metrics this was true. Diversity, evenness, and dominance were significantly greater in the NBSA than in JB (Table 6-3). Number of taxa, while greater in the NBSA, was not significantly greater (p=0.058) (Table 6-3). From the results of these tests, along with the reference envelope approach, it was concluded that the BIC was comparable between the NBSA and JB.

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40	3.1	26	Please add text to clarify the relationship between individual LOE, measurement endpoints (MEs), and risk questions. Table 3-6 is helpful but the status of specific information and how it is used in developing risk conclusions should be clarified.	Text has been added to Sections 3.1 and 3.5.1 clarifying the relationship between individual LOE, measurement endpoints (MEs), and risk questions.		Response acceptable.	N/A
41	3.1.1	27	See Comment No. 5. 1st paragraph. Is there a need to consider potential exposures to contamination at depth?	See response to Comment 5.		Response acceptable.	N/A
42	Table 3-1	-	Due to the very limited insect fauna associated with estuarine habitat such as NBSA, please use the term "invertivore" rather than "insectivore" throughout the document.	The term "invertivore" has replaced "insectivore" throughout the document.		Response acceptable.	N/A
43	3.1.2	27	Please include the available fish community dataset (including the ichthyoplankton data) as a separate LOE in the analysis. A quantitative analysis of the historical data is not possible but a qualitative evaluation relative to expectations (including other estuaries) would be useful.	Comparability of the NBSA fish community to that of other mid-Atlantic estuaries has been added as a risk question in Section 3.1.2. This risk question has been evaluated in Section 7.1 Fish Community Assessment. The evaluation has been added as a line of evidence in Table 7-24 and Table 11-1a.	See Comment #4.	To support the proper use of the non-HQ LOEs in the WOE integration process, it is important that the reader understand the study limitations and what inferences are supported by this dataset. The answer to the risk question (Section 3.1.2) "Are fish communities in the NBSA different from those found in similar nearby water bodies" is ambiguous, but without comparative long-term data for an appropriate reference estuary or statistical power defined, it is impossible to determine whether chemical stressors in the Bay are impacting the NBSA fish community or not, based on this historical dataset. This LOE should not be used in the WOE integration process to identify preliminary COCs but rather summarized with relevant uncertainties noted for consideration by the risk managers. Given the significant differences between the objectives of the ABS program and a study designed to determine whether contaminants were affecting the fish community, it is misleading to conclude that the fish community in the NBSA is "comparable to other areas in the NY/NJ Harbor Estuary". Rather, as noted in Section 7.1.3, differences between the study areas were noted in the ABS study and the study was not designed to determine the specific causes for these differences.	The fish community analyses are discussed within the context of uncertainties and limitations in the ABS sampling design in Section 7.6.1. The text of this section has been modified to discuss the limitations on the use of the historical datasets. The fish community LOE is not used to select preliminary COCs in Section 7. It is only used as a supporting LOE (along with the other LOEs) to characterize the potential for risk from the preliminary COCs from the HQ analyses. While the ABS survey was not designed to statistically compare the NBSA to other NY/NJ Harbor Estuary locations or to test whether any differences among locations were specifically COPEC-related, the data do show that ichthyoplankton and adult demersal finfish abundance and diversity in the NBSA are similar to or greater than other locations in the NY/NJ Harbor Estuary. It is very unique to have multiple years of detailed fish community data like this for a Superfund site. These data are very informative, and are framed in this BERA for the USEPA to consider in future risk management decisions.

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44	3.1.3	28	Please indicate that the specific LOEs for this AE, which include the bird egg evaluation, are presented in Section 8.	The text has been revised to state that the LOEs are presented in Section 8.		Response acceptable.	N/A
45	Figure 3-2	-	Due to the brackish conditions in the Bay, it is likely that it provides foraging habitat for true insectivores. Consequently, suggest changing the term (here and in Figure 3-3) and checking the text for consistent usage. Also, are bats considered to be likely receptors in NBSA (as shown on the figure)? Finally, please change the term "fisherman" to the more gender-neutral term "angler" for consistency with the Baseline Human Health Risk Assessment (BHHRA).	The Bay is saline, not brackish. Insects do not inhabit or hatch in saline waters. This issue was discussed in prior meetings and calls between GSH and the USEPA when the selection of receptors for this BERA was made and agreed upon. Therefore, changes are not proposed in response to this portion of the comment. Bats are not a likely receptor for the NBSA, as they are insectivores. The term fisherman has been changed to angler.		The response is unclear. If there is agreement that emerging insects are not expected in NBSA then please eliminate the bat and swallow symbols and change "insectivorous" to "invertivorous" consistent with Figure 3-3 and the revised text. Note one clarification that the original comment meant to suggest that it is unlikely that insectivores would be exposed in Newark Bay due to the saline conditions (this is consistent with Comment #46 and changes made in the revised document).	The bat and swallow images and reference to insectivores in Figure 3-2 were removed.
46	Figure 3-3	-	See Comment No. 42 regarding use of the term "insectivore". Also, the CSM indicates that the surface water (drinking) pathway was evaluated for wildlife. This pathway was not evaluated in the BERA and is unlikely given the brackish conditions throughout the Bay. Please revise the figure to indicate that this is considered an "incomplete" pathway for these receptors. Also, note that the contaminated tissue consumption pathway is technically complete for some components of the plankton (ichthyoplankton) and benthic invertebrate community receptor categories; please add a footnote to clarify. Why is the exposure pathway from subtidal sediments to invertivorous birds not considered complete? Contaminant transport from bedded sediment to the water column is not indicated and should be added.	The Bay is saline, not brackish. Surface water is not a viable exposure pathway for wildlife except through incidental ingestion while foraging, but this issue is addressed in Section 5 of the BERA. See response to Comment 47 regarding changes to Figure 3-3 to make it consistent with the USEPA-approved LPRSA ecological CSM.		While it is desirable that the CSMs for individual OUs be as consistent as possible, the overriding interest is that the NBSA CSM reflect all important, site-specific attributes that could affect receptor exposures, and some differences between the two BERAs would be expected. It is more important that Figure 3-3 accurately capture all potential receptors and pathways rather than being consistent to the OU4 BERA. The GSH response doesn't address several of the comments raised on the draft document and these need to be incorporated into the next document version. Specifically, the drinking water ingestion pathway for wildlife should be considered "incomplete" or if incidental ingestion of water during prey consumption is preferred, then an open circle, as this pathway was definitely not quantitatively evaluated in the NBSA BERA. Also the incomplete prey consumption pathway for plankton and benthic invertebrates is not correct for all class members so please ensure that this qualification is made by either adding a footnote to Figure 3-3 or discussing in the text. Also, see back-check comments on Comment #47.	Figure 3-3 was revised to show the drinking water ingestion pathway for both surface water and groundwater as incomplete for all receptors.

A footnote was added to Figure 3-3 that explains differences in the tissue exposure pathways for carnivorous and herbivorous/filter-feeding plankton and benthic invertebrate receptors. |

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47	Figure 3-3		Please include more rationale for the categorization of exposure pathways in Figure 3-3 and consider adding a new category (oval with stippling?) to identify likely complete and major pathways that are only qualitatively evaluated (appropriate for crustaceans ingesting contaminated prey?). Suggest adding footnotes to qualify as necessary.	Figure 3-3 has been edited to be consistent (structure, content, and categories) with the USEPA-approved ecological CSM from the final LPRSA BERA. It includes the receptor categories and exposure pathways agreed upon with the USEPA and evaluated in this BERA for the NBSA food web. It is important to keep these CSMs consistent as the food webs are similar in terms of the types of organisms evaluated, exposure pathways, sources of COPECs, and methods for assessment of risk in the respective BERAs.		See Comment #46.	See response to Comment 46.
			(1) Why is the tissue ingestion pathway for benthos (predators) considered incomplete?			See Comment #46.	See response to Comment 46.
			(2) For reptiles, Chapter 10 presents a qualitative evaluation of potential pathways so shouldn't a different symbol be used throughout?			Response acceptable.	N/A
			(3) Why is the ingestion of subtidal sediment not considered a major pathway for some species such as the scaup?			Addressed by aggregating all sediment zones.	Acknowledged as addressed.
			(4) Why is groundwater considered the only transport mechanism for channel sediments; what about deposition of particulates?			Addressed by aggregating all sediment zones.	Acknowledged as addressed.
48	3.3.1	31	Please discuss the designation of the wildlife surface water drinking exposure route as "incomplete" in this section.	This comment has been addressed.		Response acceptable.	N/A
49	3.3.2	32	While EPA believes that the BERA study components were conducted at a spatial scale appropriate for the risk analysis, it should be recognized that higher resolution (i.e., finer-grained) information may be necessary to support decision making in the FS or post-ROD stages. This is particularly the case for individual tidal wetlands and mudflats. As part of the uncertainty assessment, please discuss the importance of spatial scale in decision-making and the utility of Phase III sediment chemistry data available for these habitats in applying BERA conclusions to make decisions at smaller scales (e.g., should tidal wetland X be remediated or not?).	A discussion of spatial scale has been added to the uncertainties assessment of Sections 6 through 9. Additional text has also been added to Section 11 to discuss this issue.		Response acceptable.	N/A

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50	3.3.2	32	The 14 December 2018 SQT update meeting in Edison, NJ included a discussion concerning the potential impact on the North and Southeast zone EPCs, depending on which was to include the CDF area. EPA understands that GSH evaluated this issue and determined that the choice of zone in which to include the CDF was inconsequential. Please include this analysis and a summary of the findings in the BERA.	Based on discussion with EPA and the bioaccumulation modeling team, the area of the CDF cell has been reassigned to the Southeast BERA Assessment Zone in the revised BERA. All EPC calculations have been revised to reflect this change. The change only affected eight sediment samples that were collected in that area. This change made the EPC concentrations greater in the North assessment zone for most COCs, usually no more than 10% greater. Since GSH is in agreement with EPA on moving the CDF to the southeast zone, no additional analyses were deemed necessary to add to the BERA. Figure 3-4 and Table 4-9 have been revised accordingly.		Figure 4-3 (not 3-4) and Table 4-9 have been updated and the latter now shows additional shoreline samples (51 rather than 31) - deltas are 5, 9 and 11 for N, SE and SW, respectively (previous table had only 16, 5 and 5 so missing 5). Please distribute polychaete sampling locations among zones so that the reader can understand relative distribution (even though data are only evaluated bay-wide). Also, please see Comment #53 and indicate that the CDF is now placed in the Southeast zone.	Figure 3-4 (Newark Bay Sampling Locations and Assessment Zones) was updated to reflect that the Newark Bay CDF was now within the SE zones. Figure 4-3 was revised to show the EPA subunits under which the Phase III sediment sampling was conducted (Tierra 2016). Table 4-9 was revised to show the distribution of polychaete samples among zones. Shoreline sample numbers have been revised to indicate that all shoreline samples were included for analysis. Figure 4-4, Tables 4-9, 4-10, and Appendix C-1 have been revised and are now consistent.
51	3.3.2	32	Please explain why channel exposures were only evaluated qualitatively in the BERA (e.g., difficulty in collecting data from actively used navigation channels; contamination addressed by other regulatory programs).	This comment has been addressed.		Response acceptable; however, see Comment #18 and explain why limited data were collected from the channels (e.g., ship traffic limited biota sampling, contaminant uptake lower for over-wintering organisms, etc.).	The contamination in the regularly dredged navigation channels is evaluated and addressed by the USACE as part of the permitting process for the navigation dredging events. This is stated in Section 3.3.2. See also response to Comment 18.
52	Table 3-3	32	See General Comment No. 9. Please provide information on which sediment samples are associated with each assessment zone and habitat category in an Appendix [this is done for Sediment Quality Triad (SQT) samples in Appendix D but not for the full Phase III dataset]. Also, for the sandpiper, heron and muskrat, clarify the distinction between prey foraging areas and areas where they may be exposed to contaminated sediments directly. For instance, wading birds are assumed to incidentally ingest sediments only from mudflats but are assumed to potentially forage for prey throughout the entire bay or individual assessment zone. Please make sure that all assumptions are clearly indicated and consider adding a table to summarize. Also, please clarify that vegetation consumption by the muskrat is assumed to be co-located	See response to Comment 9 above. Tables have been added to Section 4 that list the sediment and tissue samples associated with each of the BERA assessment zones. Figure 4-4 shows the locations of sediment samples on a map. Also, text has been added to Sections 4, 7, 8, and 9 to discuss specific exposure assumptions for the receptors evaluated.		Response acceptable.	N/A

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			with the shoreline areas (i.e. using transfer factors to estimate exposure via this pathway) but other dietary components are based on samples collected bay wide or from individual assessment zones.				
53	Figure 3-4, Table 4-10, and Appendix C Tables	-	Please reference the list of samples included in each BERA assessment zone as identified in Figure 3-4, Table 4-10, and Appendix C Tables.	See response to Comment 52. New tables in Section 4 are referenced in Figure 3-4, Table 4-10 and Appendix C tables.		There is some confusion in the sediment location apportionment among datasets between Table 4-9, Table 4-10 and Appendix C-1. This appears to be due part to aggregation of intertidal mudflat samples with the broader category of "shoreline" samples (footnote to Figure 4-4 indicates that intertidal mudflats are also categorized as shoreline). Table 4-9 indicates that there are 21, 14 and 16 samples in the north, southeast and southwest shoreline category, respectively. Table 4-10 indicates that there only 16 shoreline locations (13 categorized as both intertidal and mudflat and 3 additional) in the north; for the southeast area there are a total of 6 locations (1 mudflat - incidentally please also check Station 124 in Table 4-10 as intertidal per the above footnote, 2 that are both mudflat and shoreline, and 3 shoreline only). To summarize, Table 4-10 indicates that there are a total of 32 locations that are classified as either mudflat, shoreline, or both rather than the 51 shown in Table 4-9. Table C-1 appears to be consistent with Table 4-10, so editing Table 4-9 may be appropriate. Finally, it would be helpful to clarify the separate exposure assumptions for the mudflat and shoreline areas, and indicate that the latter is considered inclusive of intertidal mudflat locations in the text when referencing Table 3-3. Please add a statistical summary of the 10 composite channel samples to Appendix Table C-1; see Comment #18.	A footnote was added to Table 3-3 clarifying the exposure assumptions for intertidal and shoreline areas. Clarifying text was added in the BERA text Section 3.3.2 when referencing Table 3-3. Summary statistics for the 10 composite regularly dredged deep water channels was added to Table 4-12. See response to Comment 18. Shoreline sample numbers have been revised and are now consistent between Tables 4-9, 4-10, and Appendix C-1. Figure 4-4 were also updated to reflect this change.

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54	Figure 2-1	-	Is the term "intertidal areas" synonymous with mudflat exposure areas? Please clarify and ensure consistency throughout the document. Also, why are extensive intertidal areas along Staten Island and in the southwest that were observed during the reconnaissance survey and the crab/clam sampling program not depicted on Figure 2-1? Please clarify or revise the figure accordingly.	Intertidal areas include intertidal mudflats, vegetated wetlands in the intertidal zone, and industrial waterfront shoreline areas that are not considered habitat, but are partially located in the intertidal zone. The intertidal habitats in the NBSA are limited. The depictions in Figure 2-1 are accurate, based on available mapping and the results of the 2013 Reconnaissance Survey.		Response acceptable.	N/A
55	Figure 4-2	-	What is the difference between the intertidal geomorphic areas depicted in yellow and the purple shoreline edge? Also, how are the different observed shoreline use categories defined?	The shoreline edges are colored according to the human use categories described in Section 2.1.2. Purple indicates a recreational land use adjacent to the shoreline. See also responses to Comments 13 and 14.		Response acceptable.	N/A
56	3.4	33	Please clarify that a Frequency of Detection (FOD) threshold was used to identify Contaminants of Potential Ecological Concern (COPECs) considered in the Multivariate Analysis (MVA).	All detected chemicals were considered in the SQT. Section 6.1.2.3.1 describes how the final list of chemicals were chosen for the principal component analysis. A detailed discussion is included in Section 3.2 of Appendix A of the BERA.		The original comment referred to the potential inconsistency between the language in this section and that in Appendix A, Section 3.2.2, paragraph 2, where the last sentence indicates: "Chemicals with a FOD of less than 80% were excluded from the exploratory analyses due to the potential for adding additional unexplained variability." As indicated in the response, the process is discussed in Appendix A.	The following sentence has been added to Section 6.1.2.3.1: "Chemicals with a FOD less than 80% were excluded from the exploratory analyses due to the potential for adding additional unexplained variability."
57	3.5.1	35	See Comment No. 40 regarding terminology for LOE and measurement endpoints.	See response to Comment 40.		Response acceptable.	N/A
58	3.5.2	36	Please provide a summary of the general components of the LPR 17-mile RI/FS TRV development process, including the approach to developing SSDs. A discussion of the criteria used in selecting specific studies would be helpful in understanding the degree of conservatism relative to the FFS values.	This comment has been addressed.		Response acceptable.	N/A
59	3.5.3	36	Consistent with the 17-mile LPR BERA, risks based on both 17-mile LPR BERA/NBSA BERA and LPR FFS TRVs should be carried through the document on equal footing and summarized in the risk conclusions. In addition, all discussions concerning TRV uncertainties need to be revised	See response to Comment 3.		See Comment #3. This response will be evaluated following revisions to Appendix D based on supplemental comments.	See response to Comment 3 and supplemental Appendix D comments 187 - 253 below.

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			following revisions to Appendix D to ensure that the presentation is fair and balanced and acknowledges the relative uncertainties associated with both sets of TRVs. See Comment No. 3.				
60	3.5.3	38	See Comment No. 8. Consistent with the 17-mile LPR BERA, please include all receptor-COPEC combinations with NOAEL- or LOAEL-based HQs >1 inclusive of both NBSA and LPR FFS TRVs as "preliminary COCs". Finally, all COPEC-receptor pairs where "unacceptable risk is uncertain" should also be carried forward for additional evaluation in the FS. Note that final COCs will be determined in consultation with EPA. Also, please make sure that this section is consistent with Section 11.1.	See response to Comment 8.		See Comment #3. This response will be evaluated following revisions to Appendix D based on supplemental comments.	See response to Comment 3 and supplemental Appendix D comments 187 - 253 below.
61	3.5.3	38	Please clarify apparent discrepancies with Section 11.1, including whether the intended objectives of selecting "risk drivers/COCs" and identifying "COCs for risk management considerations in the FS" are the same.	See response to Comment 8. Section 11 will be modified to distinguish between preliminary COCs and risk drivers. Each of these will be considered in the FS.		Response acceptable; however, please see Comment #3 regarding the identification of preliminary COCs.	See response to Comment 3
62	4.2.1	40	Item No. 3. When a field duplicate and parent sample are both reported as non-detected, the sample pair is represented by the lower of the two reporting limits, which would bias the representation of this sample pair low. This bias appears to contradict the discussion of calculating totals in Section 4.2.2 (page 41) where a total is represented by the highest reporting limit when all the targets in the total are reported non-detected. Please clarify this apparent discrepancy, and for the field duplicates, please consider representing the sample pair by the highest reporting limit when both the field duplicate and parent sample are reported as non-detected.	As discussed and agreed upon in a conference call with the USEPA team on June 13, 2019, and a follow-up e-mail dated July 15, 2019, EPA agrees with GSH's approach for the handling of non-detects in field duplicates. No change was made.Regarding the summation of totals, the detection limit in one compound does not necessarily give information about another. Therefore, the highest detection limit of all the compounds is chosen as the detection limit for the summation. This treatment of totals has been consistent through all phases of the RI. No change was made.		Response acceptable; however, please refer to follow-up email dated August 2 where EPA requested a sensitivity test on Total DDx and Total Chlordane to confirm that summations using zero did not bias the conclusions of the risk assessment.	Sensitivity/uncertainty analyses for all totals summations (PAHs, TEQ, PCBs and DDx) were completed and are included in Appendix F and summarized in the main document. They are shown as sum of detects only, sums with 1/2QL substitution and full QL substitution. No further revisions are needed.
63	4.2.1	40	In the last sentence, should the text read "….the higher of the two detection limits …" consistent with	The sentence as written is correct. See response to Comment 62.		Response acceptable.	N/A

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			language in the last sentence in Section 4.2.3? Please revise as necessary.				
64	4.2.2	40	Please identify which total concentrations were reported by the analytical laboratory.	The total concentration of each of the eight dioxin/furan homologue groups was reported by the laboratory. A footnote has been added to the text.		Response acceptable.	N/A
65	4.2.2	41	Last paragraph, after list. The BERA states that "The totals listed above were only calculated when all the individual analytes comprising the total were analyzed." During the Phase III sediment program, all samples were analyzed via Method 1699 for chlorinated pesticides. Please clarify when a sample was not analyzed for all target pesticide analytes; otherwise, it is anticipated that in all cases the target parameters would be included in the database as detected, non-detected, or rejected.	The reviewer is correct. All sediment and tissue samples were analyzed via Method 1699. This sentence has been deleted.		Response acceptable.	N/A
66	4.2.2	41	Please describe the types of situations where not all analytical parameters were analyzed in a sample and how frequently this occurred.	See response to Comment 65. The sentence has been deleted.		Response acceptable.	N/A
67	4.2.4.1	42	1st paragraph. Regarding adsorption of contaminants to fine-grained particles, please add to the discussion that surface area affects adsorption more than mineralogy. In a hypothetical scenario with the same minerals, fine-grained particles would adsorb more contaminants than coarse-grained particles with the same mineralogy because fine-grained particles have more surface area for adsorption.	The fifth sentence has been revised to state: "This affinity is related to the surface area of the particles since fine-grained particles have more surface area for adsorption."		Response acceptable.	N/A
68	4.2.4.1	43	3rd paragraph. The BERA states that Lithium could be used to normalize metals concentrations. Please note that the Phase III sediment samples were not analyzed for Lithium, so no correlation/normalization of this type would be possible.	This sentence is referring to potential normalizing constituents discussed in the literature in general. However, lithium has been deleted from the list of potential normalizing constituents since it was not analyzed in the NBSA.		Response acceptable.	N/A

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69	4.2.4.2	43	Please add text noting that lipid levels vary seasonally in organisms (depending on reproductive state) and can also be influenced by a number of environmental factors, including quality of food and stress levels in the organism. Please also mention that some of the collected clam samples had unnormally low lipid content.	Text has been added noting the seasonal variation in lipid levels in biota and the relatively low lipid levels in softshell clam tissue.		Response acceptable; however, please reference data for comparable estuaries to provide perspective. For instance, Lohmann et al 2004 (ETC) found lipid levels in adult M. arenaria collected from several sites near Boston, MA ranged from 5.3 - 9.0% (dw basis).	References to lipid levels in clams from other studies have been added to Section 4.2.4.2.
70	4.2.6	44	Please explain how an Upper Confidence Limit (UCL) was selected when the software recommended multiple values. Also, was the EPA worksheet used to estimate Kaplan-Meier Toxic Equivalency (TEQ) for dioxins/furans and coplanar polychlorinated biphenyl (PCB) TEQ calculations for individual samples? If not, the uncertainties should be discussed in the treatment of non-detects.	When multiple values are recommended, they are all considered valid UCLs and in general, multiple recommended values are very similar and the selection is of no consequence. If multiple UCLs were recommended by ProUCL, the lowest value was selected for the BERA. Clarifying text has been added to Section 4.2.6. USEPA guidance does not prescribe a calculation method for TEQ (USEPA 2008). TEQ was calculated as the sum of the detected congeners multiplied by the World Health Organization (WHO) toxicity equivalence factors (TEFs) specified in the guidance (USEPA 2008). Uncertainty with respect to non-detects was evaluated by also presenting the TEQ values as the sum of detected congeners with either ½ the detection limit or the full detection limit substituted for non-detects as suggested in the guidance (USEPA 2008). Clarifying text has been added to Section 4.2.3.		USEPA directed that the exposure point concentration calculations for the LPR and Newtown Creek BERAs should mirror the approach used in the corresponding BHHRAs and for the sake of consistency, the NBSA BERA should have evaluated use of the EPA Kaplan Meier Calculator (EPA, 2014) in the calculation of TEQs, as was done in the LPR and NBSA BHHRAs. The calculator is recommended as a tool for avoiding potential biases in the derivation of EPCs and considers rejected values, unlike ProUCL; however, the evaluations conducted in the NBSA BHHRA and LPR OU4 BERA sensitivity analysis determined that the different approaches for calculating TEQs were very similar.	Comment noted.
71	4.2.7	44	2nd paragraph. Using half the Reporting Limit as a substitution for nondetected concentrations is common practice for non-isotopic dilution methods (such as Metals). It is not acceptable for isotopic dilution methods (such as PCB, dioxins/furans, and Pesticides) where the lowest reliable Reporting Limit is the sample-specific Estimated Detection Limit. Please revise handling of non-detected concentrations accordingly.	As discussed and agreed upon in a conference call with the USEPA team on June 13, 2019, and a follow-up e-mail dated July 15, 2019, for all analytical methods, the reporting limit (RL) is the quantitation limit (QL). Clarifying text has been added to Section 4.2.7.		Please clarify response. EPA agrees that non-detected concentrations can be reported to the quantitation limit (QL); however, the Reporting Limit (RL) in the database is not always equal to the QL. Please ensure that non-detects are set equal to the QL column in the database.	After discussion/clarification with GHD regarding the field definitions in the GHD database, Arcadis amends their initial response to comment as follows: "*For all analytical methods, non-detect values were reported to the quantitation limit.*" The text in Section 4.2.7 was revised. In addition the terms "reporting limit" and "detection limit" have been globally replaced by the term "quantitation limit."

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72	4.2.7	44	3rd paragraph. Please include a discussion on handling non-detected concentrations for non-isotopic dilution methods versus isotopic dilution methods. As discussed during the resolution of the NBSA database, the Reporting Limit (RL) for non-isotopic dilution methods is equal to the Quantitation Limit (QL), whereas the RL for isotopic dilution methods is the sample-specific Estimated Detection Limit (EDL).	See response to Comment 71.		Refer to Comment #71.	See response to Comment 71.
73	4.2.7	44	4th paragraph. Please include a discussion for handling rejected data. Polychlorinated Dibenzo Dioxins and Furans (PCDD/F) congeners and dioxin-like PCB congener samples with rejected data are to be added to the EPA Kaplan Meier spreadsheet at the concentration of the laboratory Method Detection Limit (MDL) to calculate TEQ.	Rejected data are defined as providing no information related to the observed concentration and therefore are not classified as detects or non-detects. In any case, there were very little rejected data that would impact TEQ calculations. For example, only four sediment results were rejected for any dioxin, furan or dioxin-like PCB and the rejected compound (i.e., 1,2,3,4,7,8-Hexachlorodibenzofuran) has a low TEF (i.e., 0.1). See response to Comment 70 regarding TEQ calculation. Rejected data were not added to the BERA as described in the text in Section 4.2 (first paragraph).		Response acceptable but see Comment #72 as EPA guidance (2014 TEQ calculator) suggests considering potential bias introduced to the TEQ calculations by rejected data.	See also Comment 70.
74	4.2.8	44	1st paragraph. A brief discussion of how detected and non-detected results are indicated in the box plots and the utility of these box plots to identify potential outliers would be helpful. Please also summarize or reference the footnotes to Figures 4-3 and 4-4.	The text has been revised to explain how outliers and non-detected results are depicted in the box plots as described in the footnotes to the box plots (Figures 4-4 and 4-5).		Response acceptable.	N/A
75	4.2.8	44	Please explain why contaminants with less than 8 samples were removed from the ANOVAs. In addition, since the data were log-transformed, the results of the ANOVAs should be discussed in terms of log-concentrations, not the original concentrations.	This statement has been removed. No data were removed from the ANOVA analyses presented in the BERA.		The question of the discussion of ANOVA results in terms of log-concentrations was not addressed in the revised BERA; please incorporate this comment.	The following sentence has been added to Section 4.2.8 regarding ANOVA analyses: "Log-transformation results in the comparison of geometric means, however, under the assumption of equal variance, differences in means are inferred when differences in geometric mean are statistically significant."

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76	4.3.2	46	Sentence between bullets. Please state that no water column samples were collected from the NBSA during low flow conditions, per the Small Volume Chemical Water Column Monitoring (SV-CWCM) Quality Assurance Project Plan (QAPP), because during low flow conditions the LPR's interaction with the NBSA is diminished.	Text has been added stating that no water column samples were collected from the NBSA during low flow conditions because during low flow conditions the LPR's interaction with the NBSA is diminished.		Response acceptable.	N/A
77	4.3.2	46	Last paragraph. Please provide a frame of reference for the statement "concentrations of COPECs in surface water were low" (e.g., low ppb range for organics?)	This statement has been removed.		Response acceptable.	N/A
78	4.3.3	47	2nd paragraph. Please qualify that the human health data use objective is associated with the direct contact exposure pathway.	Text has been added to clarify the objective of the sampling.		Response acceptable.	N/A
79	4.3.7.1	49	Please include a reference to Figure 6-1, which shows the locations of the 8 polychaete bioaccumulation samples.	A figure reference has been added.		Response acceptable.	N/A
80	Table 4-4	-	A review of the BERA tables shows that different reporting and detection limits were used to represent non-detected results compared to the Newark Bay May 2019 database. It appears that the BERA tables were created using the older December 2018 database. Please correct the database (several examples follow below):	The statement in the comment that "It appears that the BERA tables were created using the older December 2018 database" is true, as the revised database was not available until May 2019, after the Draft BERA submittal. All data analyses, summations, and food web modeling/HQ calculations have been updated in the revised BERA using the May 2019 version of the database.		Response acceptable.	N/A
			· Example #1: According to Table 4-4, the maximum non-detect PCB 1016 result was 565 ng/kg in sample NB03SED-CHM194 based on the reporting limit in the September and December 2018 databases. According to the May 2019 database, the maximum non-detect PCB 106 concentration was 192 ng/kg in sample NB03SED-CHM194, based on the corrected reporting limit.			Response acceptable.	N/A
			· Example #2: According to Table 4-4, the maximum non-detect dieldrin result was 10.5 pg/g in sample NB03SED-CHM350 based on the reporting limit in the September and December 2018 databases. According			Response acceptable.	N/A

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			to the May 2019 database, the maximum non-detect dieldrin concentration was 3130 pg/g in sample NB03SED-CHM350, based on the corrected reporting limit.				
			· Example #3: According to Table 4-4, the maximum non-detect 1,2,3,4,7,8,9-Heptachlorodibenzofuran (HpCDF) result was 4.95 ng/kg in sample NB03SED-CHM354 based on the reporting limit in the September and December 2018 databases. According to the May 2019 database, the maximum non-detect 1,2,3,4,7,8,9-HpCDF concentration was 0.0372 ng/kg in sample NB03SED-CHM354, based on the corrected reporting limit.			Response acceptable.	N/A
			· Example #4: According to Table 4-4, the maximum non-detect Chromium VI was 1.4 mg/kg in sample NB03SED-CHM161 based on the reporting limit in the September and December 2018 databases. According to the May 2019 database, the maximum non-detect Chromium VI was found at 4.1 mg/kg in sample NB03SED-CHM161, based on the corrected reporting limit.			Response acceptable.	N/A
81	Table 4-4	-	Please clarify the incorporation of rejected data into the BERA. For example, it appears the rejected data for 2,4'-DDE, 2,4'-DDD, and 2,4'-DDT in sample NB03SED-CHM339 were included in BERA Table 4-4.	Table 4-4 has been corrected, the rejected data for 2,4'-DDE, 2,4'-DDD, and 2,4'-DDT in sample NB03SED-CHM339 were not included in Table 4-4. The Total DDx (2,4) Total Fraction in sample NB03SED-CHM339 is also not included since it could not be calculated from the rejected data.		Response acceptable.	N/A
82	4.3.6	48	1st sentence. Is "campus" missing? Please revise as necessary.	The sentence is correct as written.		Response acceptable.	N/A

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83	4.3.6	48	1st paragraph. During the discussion of the "SQT and Porewater Data Report," it was agreed that the uncertainty in the porewater concentrations (due to the various possible literature reference values for partition coefficients) would be evaluated in the BERA (refer to EPA's back-check of Tierra Solutions' responses to comments dated March 16, 2017). Please add the requested evaluation to the document.	The uncertainty of porewater concentrations is discussed in Section 6.4.1 of the BERA (also in Appendix A). Section 4.3.6 now includes a statement directing the reader to Section 6.4.1 where the uncertainty is discussed. Recent EPA guidance (USEPA/SERDP/ESTCP 2017) indicates that K_{PE} values could vary by as much as 0.3 log units (i.e., a factor of 2). Therefore actual porewater concentrations could be as much as two times greater or lower than those estimated by the researchers at UMBC. The uncertainty discussion has been expanded to include a discussion of the implications of doubling the estimated porewater concentrations.	Please review the USEPA back-check of the Tierra response to the SQT and Porewater Data Report comments (particularly Comments #12, 13, 15 and 16) and ensure that the uncertainties associated with the porewater concentration estimates are described and evaluated in the revised BERA.	Response acceptable.	N/A
84	4.3.6	49	2nd paragraph. Please provide a summary of the uncertainties associated with these procedures, including whether there are differences across different analyte groups.	See response to Comment 83.	See Comment #83.	Response acceptable.	N/A
85	4.3.7.2	49	2nd paragraph. Please provide a reference to the discussion of how whole-body crab tissue concentrations provided in Table 4-7c were estimated based on the concentrations in the hepatopancreas, edible muscle and carcass tissues. Where are the data located and how were non-detects handled? See also Comment no. 112.	A discussion of the method for whole body crab calculations has been added (see Section 4.5). Table 4-15 gives the weights of the thirty four crabs that were individually measured and used to estimate the average fractional mass of each tissue type.	Please revise the BERA to describe the process of estimating whole-body crab concentrations as described in an email from Carlie Thompson to Len Warner (dated 1 July 2019) based on estimated mean mass fractions for carcass, muscle and hepatopancreas in 34 crabs.	Response acceptable; however, please explain why only 34 crab samples were used.	Text has been added to Section 4.5 to explain that the 34 crabs were the only crabs for which the tissue types were individually and precisely measured in each crab.
86	4.4.1, Table 4-9	51	1st paragraph. The BERA states that "The number of sediment and biota samples collected in each BERA assessment zone are listed in Table 4-9." The zones described in Table 4-9 do not match the "decision sub-units" shown in Figure 4-3, nor do they match the assessment zones shown in Figure 3-4. Please explain or add a cross-reference for the Table 4-9 zones. Please provide a reference to an Appendix table that lists the individual Phase III samples associated with each assessment zone.	Tables 4-10 and 4-11 list the individual samples and the assessment zone assignments for each.		Response acceptable.	N/A

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87	Table 4-9	52	244 sediments are indicated for the three zones (112+42+90=244) but 254 for the NBSA-wide category; were the composite samples in the navigation channel not included? Please provide a footnote explaining the discrepancy and an explanation why the composite samples weren't included, if applicable. Also, please identify from which zones the sediments used for the polychaete bioaccumulation test sediment were obtained.	The 10 composite samples were collected in the Regularly Dredged Deep Water Channels depicted on Figure 3-4 and were not included as part of the North, Southeast or Southwest assessment zones. However, they were included in the NBSA-wide assessment. A footnote has been added.		Response acceptable.	N/A
88	5	54	1st paragraph. The New York State Department of Environmental Conservation (NYSDEC) ambient water quality standards and guidance values should be included in the assessment of surface water quality. Please add the standards to Table 5-1, include them in the evaluation, and confirm or revise the conclusions regarding potential risks and importance of the surface water exposure pathway.	GSH disagrees that NYS standards are applicable. There are very few aquatic life criteria in NYS, and most only apply to fresh waters. In addition, the wildlife water standards in NYS were developed for freshwaters from the Great Lakes bioaccumulation model. These are not applicable to Newark Bay. In addition, the BERA includes an actual wildlife risk assessment with site-specific data that captures actual exposures to wildlife from food web interactions in the Bay.	NY state jurisdictional questions are under review by EPA. For the BERA revision, please provide a general comparison of the NJ and NY surface water values in the uncertainty analysis section and where appropriate a discussion of their respective relevancy (e.g., wildlife-protective values) for the SQT analysis. There is no need to revise the scoring in Table 5-1 of the draft BERA.	Response acceptable.	N/A

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89	5	54	Please update Table 5-1 with a comparison of total DDx concentrations to the NJ Chronic Water Quality Standard for 4,4-DDT (1.0 ng/L) and then revise the discussion in Section 5, given that fourteen (14) of the 30 NBSA SQT sediment samples had total DDx porewater concentrations greater than the state standard. Based on this information, total DDx should be specifically further evaluated as a COPEC for aqueous media at the site.	Total 4,4'-DDx has been added to Table 5-1 and compared to the SWQC for 4,4'-DDT as an uncertainty analysis since there are no chronic SWQC for the metabolites (i.e., 4,4'-DDD and 4,4'-DDE). While there are some exceedances, the mean concentration of Total 4,4'-DDx is below the chronic SWQC for 4,4'-DDT. In addition, the concentrations of the individual metabolites are also below chronic SWQC for 4,4'-DDT. As another line of evidence, discussion was added comparing the TRVs derived for 4,4'-DDE and 4,4'-DDT for the evaluation of risk to fish in the LPRSA (Windward 2019). Surface water concentrations in the NBSA are considerably lower than these TRVs. Therefore, no other revisions were made to the BERA with respect to the surface water evaluation. Total DDx (4,4') and total DDx (2,4' and 4,4') were evaluated as a COPEC for benthic invertebrates in the SQT assessment due to the concentrations in sediment and porewater.	This comment is withdrawn as resolution of Comment #88 will address the issue. As Arcadis noted, the comment should have referenced the pore water discussion (Section 2.3.3) in Appendix A. EPA also notes that the comparison of estimated pore-water concentrations to the NJ aquatic life criteria in the draft BERA also identified exceedances of the total DDx chronic criterion.	Response acceptable; however, given that the NJDEP criterion is specifically applicable to Newark Bay, the basis for this value should be discussed along with any observable temporal or spatial patterns in the exceedances of the 4,4'-DDT criterion by the detected total DDx concentration.	As described in Section 5, the basis for the NJDEP criterion is the protection of aquatic life. A discussion of the spatial and temporal variation of total 4,4'-DDx has been added to Section 5.
90	5, Figure 5-1	54	2nd paragraph. In Figure 5-1 the notes indicate that non-detected concentrations were incorporated at the detection limit for calculation of the percentiles and range on the box-plots; however, for the arithmetic mean, the non-detected concentrations were incorporated at half the reporting limit. Are there any concerns associated with using multiple treatments for non-detect data in the same data presentation (in terms of consistency and comparability)? Please revise Figure 5-1 and any other figure or table that may have multiple data handling procedures, as appropriate.	In all figures (e.g., maps, scatter plots and box plots) for which individual chemical concentration results are plotted, they are always shown at the value of the reporting limit and color- and/or symbol-coded as non-detects. For consistent presentation, the percentiles of the boxes are based on the individual values that overlie the boxes in the box plot figures, i.e., detected values or reporting limits for non-detects. For arithmetic mean calculations, one-half the detection limit is substituted for non-detects. Calculation of the arithmetic mean is consistent in tables and figures. Footnotes have been added to clarify handling of non-detects in figures.		Response acceptable.	N/A

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91	6.1.1.1	57	1st paragraph. Please clarify that the number of taxa was based on the number of discrete Lowest Practical Identification Level (LPIL) taxa, which is not necessarily equivalent to the number of species identified.	The text has been clarified.		Response acceptable.	N/A
92	6.1.1.1	58	1st paragraph. Consider adding a reference to Figure 4-2 along with a brief description of the locale in the vicinity of Station 148.	The reference and description have been added.		Response acceptable.	N/A
93	6.1.1.2	59	Please include variability statistics (CVs) for the bioassay endpoints in Appendix A and summarize them in this section. Also, please note that the variability in sublethal endpoints in the NBSA samples should not be compared to Eickhoff (2014), where mean control survival for the 28-day was 96-99%; the mean control survival for the 28-day toxicity test was 81% for the NBSA which barely exceeded the minimum survival – and the first 28-day test run had even lower survival and had to be re-run, exceeding the holding time and raising concerns regarding potential loss of contamination.	A table of variability statistics has been added to Appendix A (Attachment A-2) and the variability is discussed in Section 6.1.1.2 and Appendix A. The NBSA data are not being compared to the Eickhoff data. The discussion of the Eickhoff data is making the point that despite high survival and low variability in the 28-day survival endpoint, the growth and reproduction endpoints were quite variable in the control samples. This information is provided to put the variability of the chronic endpoints in context with other studies.		Response acceptable; however, please ensure that the sensitivity analysis results are discussed in the conclusion sections.	A discussion of the CV and minimum detectable difference (MDD) for the 28-day survival endpoint and the number of stations that would be toxic based on a relaxed definition of toxicity (i.e., 28-day survival less than 80% of control regardless of statistical significance) has been added to the tables that summarize conclusions, Tables 6-17 and 11-1b.
94	6.1.1.2	59	3rd paragraph. Please discuss if the selected SQT scoring criteria for the laboratory bioassay endpoints are different from those used in the 17-mile LPR BERA.	The scoring criteria for the LPR was to compare the bioassay results to reference threshold values. The scoring criteria for the NBSA was to compare bioassay results to the laboratory control since there were no *L. plumulosus* reference samples available for the NBSA. All endpoints were equally weighted in both BERAs. And the three "legs" of the triad had equal weighting in both BERAs. The text has been clarified.		Response acceptable.	N/A
95	6.1.1.2	60	Last paragraph. Please indicate how many stations met the criteria of control-normalized 10-day amphipod survival greater than 80% and where the chemistry screen was not passed.	This information has been added to the text along with a reference to Attachment A-1 of Appendix A where this information can be found.		Response acceptable.	N/A

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96	6.1.1.3	60	This section should present an analysis of the relationships between surface sediment chemistry and porewater chemistry. Please include bivariate plots for principal COPECs similar to those presented in the 20 August 2018 SQT Update USEPA Team briefing meeting in Edison, NJ.	Bivariate plots of porewater vs. sediment concentrations have been added as an attachment to Appendix A (Attachment A-4). They are discussed in Section 2.3.5 of Appendix A and in Section 6.1.1.3.3 of the BERA.	Table A-21 ("potential COCs") provides a logical basis for identifying a subset of chemical parameters for bivariate plot development and text discussion. EPA specifically recommends focusing on 2,3,7,8-TCDD, total PCBs (sum of 209 congeners), total DDx, dieldrin, HMW PAHs, arsenic and mercury.	Response acceptable.	N/A
97	6.1.1.3.1	60	While it is certainly true that the sediment chemistry thresholds "were derived from field sediments with chemical mixtures" (Section 6.3.1 on pg. 75), the sediments in the NBSA represent chemical mixtures. Assessing chemicals one-at-a-time ignores the reality of exposure to field-collected sediments. Please also consider applying field-tested mixture models, such as the probability of toxicity models developed specifically for the NY/NJ Harbor sediments and validated with NY/NJ Harbor-independent data of amphipod toxicity (Field and Norton, 2014) or the national ERM-quotient model that has been used successfully at numerous locations around the country (Long *et al.*, 2006). Both of these models, along with the national probability model used to derive the T20/T50 values used in the BERA (USEPA 2005), had high (< -0.3) Spearman rank correlations with *Leptocheirus* 28-day survival and growth. These correlations were greatly improved when samples with low percent fines (13 samples with <50%) were excluded. The fact that 43% of the SQT toxicity samples were collected from areas with low percent fine-grained sediment, which are both important benthic habitats and areas where contaminants are likely deposited, adds to the uncertainty with interpreting the SQT results and their application for decision-making.	Field and Norton (2014) concluded that the nationwide Pmax model from their earlier publication (USEPA 2005) performed as well or better than the region-specific models. Strictly speaking, the Pmax model is not a mixture model. The Pmax model states that the probability of toxicity is predicted by the maximum of the predictions of the individual chemical models developed by the authors. So comparing samples to the individual T20/T50/T80 and scoring the sediment based on any single exceedance is essentially the same as applying the Pmax model. For example, if a sample exceeds the T50 for any individual chemical the Pmax model predicts toxicity. This is exactly how the scoring was conducted because any station that had a T50 exceedance was given the worst possible SQT score (i.e., 1). All but one station had at least one T50 exceedance (Table A-16).

An ERM quotient is the sum of each chemical concentration divided by its ERM. The ERM quotients were calculated according to Long et al. (2006) and are presented in Table A-16 of Appendix A. The scoring was adjusted such that stations with an ERM quotient > 1 were given a score of 1 for sediment chemistry (see Table A-15). All stations had ERM quotients greater than 1. This change in scoring only affected one station (i.e., 155), which had an ERM quotient greater than 1 but no T50 exceedances. This station's sediment chemistry score was | Per agreement on the July 29th call, the PAH mixture model evaluation will be added to the BERA. Please revise Section 6.1.1.3.1 to discuss the available sediment contaminant mixture approaches and either incorporate into the analysis as appropriate or evaluate in the uncertainty discussion and demonstrate that their consideration does not affect the overall sediment assessment conclusions. | Response acceptable. | N/A |

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				changed from 0 to 1 in the revised BERA based on the ERM quotient criteria.			
				GSH disagrees that the grain size distribution of the SQT samples adds uncertainty to the interpretation. Where percent fines is defined as the percent passing the #200 sieve, only six of the 30 SQT samples had percent fines less than 40% and only nine had percent fines less than 50%. The SQT sample locations were collected under the approved SQT QAPP in consultation with EPA and are representative of the NBSA.			N/A
98	6.1.1.3.2	61	1st paragraph. Please correct misspelling of 'SWQC'. Also, please include consideration of available New York water quality standards (6 CRR-NY 703.5) for COPECs in the evaluation. See Comment No. 89.	The misspelling has been corrected. The NYS standards are not applicable to porewater in the NBSA. See response to Comment 88.	See Comment #88.	As ARARs for a portion of the NBSA, the NYSDEC surface water standards should be referenced. The technical rationale for not using these criteria in the evaluation of either surface water or porewater EPCs can also be added to the text.	The following has been added to the text of Section 6.1.1.3.2: "Because a portion of the NBSA is in the state of New York, the New York State Department of Environmental Conservation (NYSDEC) ambient water quality standards were reviewed. NYSDEC applies only acute aquatic water quality criteria to saline waters and New Jersey SWQC were equal or greater to the NYSDEC standards and are therefore protective based on NYSDEC standards."
99	6.1.1.3.2	61	Evaluating the porewater chemicals individually ignores the effects of chemical mixtures. Individual PAHs and PAH sums were evaluated separately. Toxicity related to PAH toxic units, rather than individual chemicals, should be evaluated together with other organic chemicals by combining the fractional contributions of all narcotic chemicals present (Burkhard *et al*., 2017). Please consider estimating toxic units (PAHs, mPECqs) and discussing the results in Section 6 to support the discussion of potential effects of contaminant mixtures.	An evaluation of the PAH toxic units has been added to the BERA in Appendix A and is also described Section 6.1.1.3. The analysis was conducted as described in USEPA (2003) and in USEPA (2017; cited as Burkhard [2017] by the commenter). Regarding mPECqs, MacDonald et al. (2000) is not relevant to the NBSA as it presents freshwater sediment quality guidelines. If the intention of the statement was to suggest an ERM-quotient approach, please see response to Comment 97.		Response acceptable.	N/A

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100	6.1.1.4 and Table 6-9	61	1st paragraph. Please consider using the "Total SQT Score" presented in Table 6-9 in the response models presented in Table 6-14. As currently presented, the BERA multivariate analysis focuses on evaluating the sediment chemistry to the 10-day and 28-day survival tests (only). The 10-day and 28-day survival tests are part of the "Total Sediment Toxicity Score" (shown in Table 6-4), which then becomes part of the "Total SQT Score" (shown in Table 6-9). The multivariate analysis and response models may yield more informative results using the "Total SQT Score."	The total SQT score is based on a categorization of discrete categories into numeric values and is not the type of variable that is expected to have a predictable relationship with sediment chemistry such as might be seen with individual toxicity endpoints and BIC metrics vs. sediment chemistry. Also, given that the score includes a sediment chemistry component, it is not good practice to model an index that contains sediment chemistry against sediment chemistry itself.	This comment is withdrawn.	Response acceptable.	N/A
101	6.1.2.1 and Table 6-11	62	Please ensure that all measurement endpoints are carried through the analysis. For instance, AVS/SEM information is provided in Table 6-11 and Appendix A (Section 2.3.4 and Table A-14); however, the conclusion that certain divalent metals could pose a chronic toxicity concern to benthos is not considered elsewhere in the report.	Consideration of the AVS/SEM evaluation has been carried through the remaining analysis and discussed in the conclusions.		Response acceptable.	N/A
102	6.1.2.1 and various Section 6 Tables		This section states "Table 6-13 summarizes the chemicals of potential concern to the BIC based on the SQT evaluation and the correlation analysis". How were the potential COPECs listed in Table 6-13 (e-page 486) derived from the underlying sediment and porewater toxicity and benthic invertebrate correlation data (Table 6-11 and Table 6-12)? - particularly when a statistically significant negative correlation was observed for a COPEC/parameter pair but not for others? For example, in Table 6-11 (e-page 446), selenium had negative correlations with growth (-0.35), number of taxa (-0.31), and density (-0.44) but was not identified as a potential COPEC in Table 6-13. In contrast, bis(2-ethylhexyl) phthalate had a negative correlation only with	Clarification has been added to the text that along with correlation to toxicity and/or BIC metrics among either sediment or porewater chemistry (or both), exceedances of sediment quality guidelines were factored into the decision since so many of the chemistry variables are highly correlated with each other. The metals presented in Table 6-13 are ones that have sediment quality guidelines associated with them that were exceeded (see Table 6-6). Bis(2-ethylhexyl) phthalate had exceedances of PEL/TELs (Table 6-6).		Response acceptable.	N/A

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			number of taxa (-0.39) but was included in Table 6-13. The process/criteria used to identify the potential COPECS in Table 6-13 should be clearly explained.				
			(a) Based on a review of Table 6-6 (e-page 438), Table 6-11 (e-page 446), and Table 6-12 (e-page 448), (at a minimum) BHCs, selenium, and heptachlor epoxide should also be identified as potential COPECs in Table 6-13.	(a) The gamma-BHC (lindane) TEL was not exceeded in the NBSA (Table 6-6) so BHCs were not included. Selenium has no sediment quality guidelines. No sediment quality guideline was available for heptachlor epoxide but it was evaluated as part of a total chlordane summation (see Table 6-6) which exceeded the TEL/PEL. Therefore, it is included in Table 6-13 as "chlordanes." There are water quality criteria for heptachlor epoxide which were not exceeded in porewater.		Response acceptable.	N/A
			(b) Table 6-12, e-page 448: a significant negative correlation between chlordanes and any of the porewater toxicity endpoints was not observed, but chlordanes are identified as a potential COPEC in Table 6-13.	(b) Chlordanes exceeded TEL/PELs (Table 6-6). Total alpha + gamma chlordane in sediment is negatively correlated with growth.		Response acceptable.	N/A
			(c) Table 6-12, e-page 448: no negative correlations were observed between PAHs and the benthic invertebrate metrics, but PAHs are identified as potential COPECs on this basis in Table 6-13.	(c) PAHs in both sediment and porewater are negatively correlated with toxicity endpoints.		Response acceptable.	N/A

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			(d) Table 6-12, e-page 448: negative correlations were observed between barium and vanadium and the benthic invertebrate metrics, but these contaminants are not identified as potential COPECs in Table 6-13.	(d) Barium and vanadium do not have sediment quality guidelines and therefore were not added to Table 6-13.		Response acceptable; however, how are COPECs without benchmarks treated in general?	Chemicals without sediment guidelines were still evaluated for correlation with toxicity or benthic effects. However, there was little evidence for barium or vanadium to be added to Table 6-13. Barium was not correlated with any toxicity endpoint and only correlated with density. Because density can either increase or decrease with impairment, this alone does not implicate barium as a chemical stressor. Vanadium was correlated with both density and taxa but not toxicity endpoints. However, vanadium was also shown in the exploratory analyses to be correlated with aluminum and therefore its occurrence is related to grain size (see Section 3.2.2 of Appendix A). Grain size was correlated with taxa and likely explains the correlation with vanadium. If any chemicals had been correlated with toxicity endpoints but did not have benchmarks, they would have been included as potential COPECs, however this scenario did not occur.
103	6.1.2.2	62	2nd paragraph. In practice, there are several approaches to consider when conducting a Principal Components Analysis (PCA), and the selection of an approach depends on how the data matrix is standardized prior to analysis. The approach conducted by GSH was based on extracting principal components from the correlation matrix of the raw data. This approach is the most common approach for estimating independent variables for multiple regression model development. As part of the BERA review, EPA also considered other approaches for standardizing the data, and it is requested that GSH evaluate these findings to confirm the PCA conclusions in the BERA.	For clarity, GSH extracted principal components from a correlation matrix of natural logarithm transformed variables to meet the assumption of approximate normality of the residuals. GSH has reviewed the attachment to the comments and has attached this to Appendix A of the revised BERA (Attachment 7) to support the findings of the PCA model in the BERA related to individual principal components. The attachment is discussed in the uncertainty section of Appendix A (i.e., Section 4.1).	EPA recommends that the following language be considered to address the EPA comment and Arcadis's request for clarification. "The BERA relies upon one of several possible ways to standardize data for the PCA analysis. Results and conclusions may at times vary with data handling methods, so EPA conducted additional analyses, to understand how results might vary when the chemistry data matrix was row-normalized to mass fraction per chemical, as opposed to column standardized, as was reported in the BERA. Row standardization to mass fraction is a common approach for chemical forensics and source identification. The PCA based on row normalization was consistent with the	Response acceptable.	N/A

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			Please refer to **Attachment A** for further details on the mass fraction using the "on Correlations" method **(Figure 1 through Figure 3)** and "on Unscaled" method **(Figure 4 through Figure 6).** It is important to note that the PCA was insensitive to these variations but did show some patterns in the Principal Component 1 (PC1) and Principal Component 2 (PC2); please consider these approaches to verify findings.	GSH has reviewed the analyses and accompanying text and agrees that the PCA on mass fractions shown in Figures 1 through 6 is not useful to identify risks associated with exposures to contaminants since the magnitude of the chemical concentrations is removed by the row sum data transformation. This analysis is discussed in Section 4.1 of Appendix A.	BERA results for predicting toxicity (Figure 3), but also provided additional insight by showing that the first two principal components of the chemistry data associated with the SQT locations can distinguish differing chemical signatures for the South, Central and North Areas (Figure 2D). This grouping of locations based on chemical composition differed from results based on row standardization reported in the BERA, which did not differentiate chemical signatures among the sample locations. For the SQT samples, the North, Central and South regions had the highest, intermediate and lowest loadings on PC1, representing primarily dioxins and furans and PCBs. This suggests a north-to-south decreasing concentration gradient in these organic chemicals, particularly dioxins and furans, from their sources in the Passaic River."	Response acceptable.	N/A
104	6.1.2.3.1	63	1st paragraph. The BERA states that entire Phase III surface sediment dataset was used in the principal component analysis. As part of the BERA review, EPA considered other historical data, as well as combinations of the 2016 Phase III samples and the 2015 SQT samples. The following combinations of data were tested to examine the sensitivity of the data used in the GSH's models:	GSH has reviewed the analyses presented in Figures 9 and 10 of Attachment A. The plots in Figure 10 are similar to the plots presented in Appendix A of the BERA in Figures A-12 (left panel) and A-15 (left panel) and support the findings of the PCA presented in the revised BERA. This analysis is discussed in Section 4.1 of Appendix A.	EPA recommends that the following language be considered in the discussion of the Attachment A figures (Figure 9 and Figure 10). "The results are similar to the PCA analysis using the 2015 SQT data only; however, it seems that PC1 scores are somewhat more predictive of both 10-day and 28-day survival tests, more clearly separating tests exhibiting low survival from those exhibiting higher survival for samples with high PC1 Scores (Figure 10)."	Response acceptable.	N/A
			· All of the 2016 Phase III samples			Response acceptable.	N/A
			· All of the 2015 SQT samples			Response acceptable.	N/A
			· 2015 SQT and 2016 Phase III data without the channel samples. (Note that the 2015 SQT samples were collected outside the channel; therefore, the Phase III samples from the channel were eliminated to determine if the channel samples could influence the PCA results.)			Response acceptable.	N/A

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			· 2015 SQT and 2016 Phase III data without the composite samples. (Note that the Phase III composite samples were eliminated to determine if the variance in the composite samples could influence the PCA results.)			Response acceptable.	N/A
			· Historical REMAP data from 2003, 2015, and 2016.			Response acceptable.	N/A
			Please refer to **Attachment A (Figure 9 and Figure 10)** for further details and consider incorporating this approach into the BERA multivariate analysis to verify findings.			Response acceptable.	N/A
105	6.1.2.3.1	63	The EPA PCA (see Attachment A) was completed with only the 2003, 2015, and 2016 historical data. Recognizing that there are some differences in analyzed chemical parameters - and reporting limits- across the historical datasets, please consider whether conducting a similar PCA analysis that includes the 1993 and 1998 REMAP data would be valuable. Evaluation of the data from the 1990s, which included a higher percentage of toxic samples, may provide additional insights regarding the relationship between contaminant exposures and laboratory toxicity.	Due to the differences in analytical methods and detection limits over time, GSH does not see the utility of incorporating the 1993 and 1998 REMAP data into the evaluation. In addition, different organisms were used (*A. abdita* vs. *L. plumulosus*). While it has been shown that both organisms have a similar ability to detect toxic samples, there still could be differences that would affect the outcome of the model.	Incorporation of historical data in which concentrations were higher and biological responses significantly stronger could provide a different perspective on the relative importance of different chemical stressors. EPA doesn't believe that the lack of a complete dataset for all analytes in all sampling events is sufficient reason not to conduct the requested analysis. Rather the additional analysis incorporating the historical REMAP data should be conducted and compared to the existing results. Of course, the uncertainties associated with use of Ampelisca (REMAP) versus Leptocheirus (NBSA RI), as well as the incomplete chemistry datasets for some earlier REMAP sampling events, should be acknowledged. Although Dioxins/Furans and PCBs are each not available for one of the historical sampling events (but not the same event), detection levels appear to be consistent across the events.	The response is partially acceptable. EPA demonstrated that an alternative model is possible for plotting toxicity data. Please evaluate the 1993 and 1998 REMAP data by summing the standardized concentrations and then plotting the sum against the 10-day toxicity test, similar to EPA Figure 11.	The 1993-94 and 1998 REMAP toxicity data have been plotted versus the sum of the standardized concentrations of the 18 chemicals listed in the Attachment to the EPA comments which is now Attachment A-7 of Appendix A. See Figure A-37 which is discussed in Section 4.1 of Appendix A.

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106	6.1.2.3.1	64	1st paragraph under bullets. Because loadings on PC1 were positive and relatively evenly distributed across all contaminants, PC1 essentially represents a nearly equal average of the standardized contaminants. As part of the BERA review, EPA evaluated an alternative approach to modeling the toxicity data. We summed the standardized concentrations and then plotted the sum against the 10-day and 28-day survival rates. Please refer to Attachment A (Figure 11 and Figure 12) for further details and consider incorporating this approach into the BERA multivariate analysis as another possible model.	The sum of standardized concentrations appears to be very similar to PC1, which is expected since PC1 explains a large portion of the variance. However, this method can't account for the other differences that were apparent based on the significance of PC2 for the 28-day survival. This analysis is discussed in Section 4.1 of Appendix A.	EPA recommends that the following language be considered to address the EPA comment and Arcadis's request for clarification. "Principal components analyses can be unintuitive. To help illustrate how the component scoring functions in this case, it is useful to note that because the loadings on the first component are very similar and positive, the PC scores can be approximated by the sum of column normalized chemical concentrations.Comparing Figures 10 and 11, it can be seen that the relationship between survival and PC1 is essentially the same as the relationship between survival and the sum of normalized chemical concentrations. In this case the PC scores are equivalent to the sum of normalized concentrations."	Response acceptable.	N/A
107	6.1.2.3.1 and Figure 6-3	64	1st paragraph under bullets. The BERA states that the entire Phase III surface sediment dataset was used in the principal component analysis, and PC1 accounts for 66.7 percent of the variation. As part of the BERA review, EPA evaluated the principal component analysis using only the 2015 SQT samples. To be consistent with GSH's analysis (and for the purpose of direct comparison to GSH's PCA results), the concentrations were log transformed before calculating the principal components via the "on Correlations" method in JMP. Although the principal component scores and loadings are similar to GSH's PCA results, the correlation between PC1 and 10-day and 28-day survival rates is better. Please refer to Attachment A (Figure 7 and Figure 8) for further details and consider incorporating this approach into the BERA multivariate analysis.	GSH considered this approach as a potential alternative to the final PCA presented in the BERA but dismissed it for two reasons: 1) For purposes of the Bay-wide prediction of toxicity, the PCA model should be based on the entire Phase III data set. 2) A rule of thumb in PCA is that the sample size should exceed 5 times the number of variables in the data set. GSH agrees that the PCA results are similar. GSH does not agree that better correlation is shown with the PCA of the SQT data only. The graphs shown in Figure 8 are similar to the graphs presented in Appendix A of the BERA in Figures A-12 and A-15. This analysis is discussed in Section 4.1 of Appendix A.	EPA recommends that the following language be considered to address the EPA comment and Arcadis's request for clarification. "Figure 8 shows that both 10- and 28-day survival are lowest when the first principal component score is near its maximum. Because there are few tests with low survival, the smooth curves shown in the figure and the models provided in the BERA are not to be relied upon strongly for identifying effects concentrations, but rather conclusions are limited to noting that effects concentrations are at least as high as 4 for 10-day survival and 5 for 28 –day survival. These results essentially provide a lower bound for the effects concentrations based on the mixture of chemicals represented by PC1, or equivalently the sum of normalized concentrations."	Response acceptable.	N/A

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108	6.1.2.3.2	65	Please confirm whether Equations 6-1 and 6-2 should include a random error term as revise as necessary.	Random error terms have been added to the equations.		Response acceptable.	N/A
109	6.1.2.3.2	66	2nd paragraph. Did the order in which variables were added in the stepwise model influence which model was determined to be best; were step-down procedures also tried and if so, was the same best-fitting model identified?	The text has been clarified. It is true that the order of variables would affect the sequential sums of squares. Variables were added in a step up and step down fashion and the marginal sums of squares were evaluated each time. Marginal sums of square are not dependent on the order of the variables in the model statement.		Response acceptable.	N/A
110	6.1.2.3.4	68	1st paragraph. Please include a bullet list of major findings in the conclusion section. Major findings include : · For the 10-day survival tests, most locations exhibited high survival on a control-adjusted basis (greater than 90 percent survival), suggesting that most locations tested were not particularly toxic as measured by this test procedure. · More 2015 SQT locations exhibited control-normalized toxicity in the 28-day survival tests; however, survival rates did not exhibit strong associations with contaminant concentrations. · The principal components analyses of contaminant concentrations in sediment indicated that most of the variability in the concentrations was explained by the first three components, with the overwhelming amount of variation explained by just the first principal component, although the degree to which this component predicts survival (in the 10-day survival test) is uncertain due to the small number (i.e., 2) of tests exhibiting mortality. · None of the principal components provided satisfying explanation of mortality in the 28-day survival tests. Samples with survival as low as 40 percent showed no correlation with any principal	The text in Section 6.1.2.3.4 of the BERA and Section 3.2.5.3 of Appendix A has been revised to include a bulleted list of findings. The lack of acutely toxic stations in the NBSA and the effect on dose response modeling is further discussed here and in the uncertainty section (6.3). Model agreement is also further discussed for the 28-day model in Section 3.2.5.1 of Appendix A. The two stations that showed the most departure from the model, 142 and 158, are further discussed with respect to their replicate variability, which may be the reason for their departure from predictions. As described in Section 3.2.5.1, other than for those two stations, the model has good predictability with respect to toxic vs. non-toxic.	EPA suggested that GSH/Arcadis should feel free to revise the suggested summary language to acknowledge concerns raised on the July 29th call. In addition, EPA suggested mentioning that the NBSA analysis is more robust than presented in many other BERAs.	This comment was only partially addressed. Please revise the conclusions to modify the word "strong." The dose response curves are described as strong relationships between survival and chemistry. The term "strong" would be acceptable in reference to the apparent step change in survival from essentially no effects to apparently strong chemistry effects. However, the term "strong" seems to be used more in reference to the strength of the model, which is not really accurate, nor is a strong model needed for classifying sediments as toxic or non-toxic. The primary utility of the model is to identify a lower bound PC score for which effects of some degree can be expected. Please also refer to Comment 111. Note that EPA is assuming that GSH is referencing Location 143 (not 142) in their response.	The word "strong" has been deleted. See also response to Comment #111 regarding the lower bound PC score. The response correctly referenced stations 142 and 158 as having the largest departure from the 28-day survival fitted model. See Figure A-16 and Section 3.2.5.1 of Appendix A.

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			component, while only two of the three samples with less than 20 percent survival coincided with a unique principal component score.				
			· Continuous models for survival can represent the distribution of the survival data but are poorly constrained where toxicity appears to change rapidly from place to place. The data are largely binary (good survival or poor survival) and do not permit an accurate estimation of intermediate conditions.				
111	6.1.2.3.4	68	1st paragraph. EPA recommends that the information provided by the 10-day survival tests be treated in a similar fashion to No Observed Effects Levels (NOAEL) and LOAEL because of the small number of 10-day survival tests that exhibited significant mortality. The level of contamination at which effects can be expected cannot be reliably identified by the distribution of the survival in the tests. Please revise conclusions accordingly.	A discussion of the uncertainty of the threshold for acute toxicity based on the PCA models has been added to Section 6.3 of the BERA and Section 4.1 of Appendix A.	Per agreement on the July 29th call, Arcadis will revise the model uncertainty section to further discuss the existing data constraints (significant toxicity and elevated concentrations at just 2 of the 30 SQT stations) and the challenges of identifying a threshold level from the model.	This comment was only partially addressed. The primary utility of the model is to identify a lower bound PC score for which effects of some degree can be expected. Please expand the conclusions in Section 6.1.2.3.4 to discuss the uncertainty of the model in defining a lower bound of no observed effects.	Section 6.1.2.3.4, second bullet, was expanded to discuss the threshold value (i.e., lower bound PC1 score) for which acute toxicity may occur.
112	6.2.1	71	Please provide details on how the individual whole-body crab samples were estimated, including how non-detects were handled.	The whole-body crab estimation is described in Section 4.5.	See Comment #85.	Response acceptable.	N/A
113	6.2.2	72	1st paragraph. Please provide backup calculations for the invertebrate TRVs for total PAHs and hexachlorobenzene, as neither could be verified.	The requested information was provided to the USEPA in July 2019.	EPA received the requested backup documentation in August 2019 from GSH. Please see Attachment A, which identifies additional comments related to the TRVs selected for the BERA.	Response acceptable.	N/A

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114	6.2.2	72	Last paragraph. While EPA acknowledges that the intertaxonomic extrapolation of mollusk tissue effects data introduces uncertainty into the risk analysis of blue crab, the primary question appears to relate to the relative sensitivity to TCDD of these taxa rather than life history differences. The LOE is based on tissue residues, so differences in life history and exposure potential are less significant. As noted in the report (Section 7.5.1), "Direct measures of COPECs in samples of (*fish*) tissue inherently integrate many factors related to fish COPEC exposure, such as site use and dietary composition, typically resulting in a low degree of uncertainty in the tissue EPCs." Little is known about how dioxin-like compounds affect invertebrates which lack the Ah receptor; however, the Cooper and Wintermyer studies suggest that invertebrates may experience subtle reproductive effects not dissimilar to biological responses observed in higher organisms. The lack of chronic toxicological data for decapods is a significant uncertainty but it would be surprising if ecologically-relevant endpoints other than survival were not identified if the appropriate studies were conducted. In the absence of site-specific tissue residue and/or chronic laboratory studies, it seems inappropriate to discount the use of the oyster results and the likelihood that residue effect levels may be similar in these two taxa. Please revise the uncertainty assessment to focus on TCDD sensitivity and ensure that the range of potential risks are carried through the risk characterization. See Comment No. 7.	While GSH acknowledges that ecologically relevant endpoints other than survival may be appropriate for blue crab, it is clear that blue crab are not as sensitive to dioxin-like effects as the eastern oyster tested in the Cooper and Wintermyer studies. The eastern oysters are not known to presently (or in the recent past) occur in the NBSA. This is likely due to a combination of habitat alterations, pathogens (i.e., dermo and MSX that wiped out much of the oyster populations in mid-Atlantic estuaries in the 20th century), and impacts from multiple contaminants. On the other hand, blue crab are abundant in Newark Bay and its tributaries despite the levels of contamination. As such, it is not reasonable to assume they are as sensitive as the eastern oyster to dioxin-like compounds or other contaminants, or substantial impacts to the populations would be expected. Consistent with our response to Comment 7, Section 6 has been revised to present the range of HQs from both the LPR FFS and NBSA LOAEL- and NOAEL-based TRVs. The uncertainties discussion has also been expanded with respect to the relative sensitivities of these organisms to dioxin-like compounds and contamination in general.		EPA disagrees that the conclusion that blue crabs are necessarily less sensitive than oyster to dioxin "is clear," as both currently occur in NBSA and the presence/absence argument is incorrect. Live oysters were observed during the 2013 Reconnaissance Survey and found abundantly at Kearny Point (in the vicinity of the Conrail Bridge remnants) and also found in numbers along the western shoreline, north of the Newark Bay Bridge. Please revise the uncertainty assessment as requested.	The text regarding blue crab vs. eastern oyster sensitivity has been removed. The uncertainty discussion on TRVs has been revised in accordance with the response to Comment 3.

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115	6.2.3	74	Please clarify as the discussion in the first full paragraph on the page is unclear – what does "evaluated in this manner" imply for the polychaete tissue data? Aren't polychaetes considered to be surrogates for other invertebrate taxa? The last sentence in the paragraph needs to be qualified or deleted.	The text regarding the use of the polychaete laboratory-derived bioaccumulation data in the tissue risk assessment has been clarified, and perspective added as to how it fits into the invertebrate risk assessment LOIs.		Response acceptable.	N/A
116	6.2.3	74	Although the laboratory bioaccumulation study was conducted primarily to support the wildlife food web exposure assessment, the data provide a distinct LOE for the benthic invertebrate assessment. Please revise the discussion of the polychaete data to emphasize the different conclusions drawn from the different LOE and acknowledge that this dataset provides a unique input to the SQT evaluation.	See response to Comment 74. The text has been revised such that the bioaccumulation study is acknowledged as a secondary line of evidence in the SQT evaluation.		Response acceptable.	N/A
117	6.2.3	74	Please summarize the NOAEL-based HQs and include in the risk summary discussion. This comment applies to the other summary discussions for assessment endpoints as well.	See response to Comment 3 with respect to consistency with the final USEPA-approved LPRSA BERA.		See Comment #3.	See response to Comment 3.
118	6.2.3	74	2nd paragraph. Please clarify the statement that elevated concentrations of NBSA COPECs do not affect the growth or survival of these organisms and explain the basis for using LPR bioassay results to infer lack of effects in the NBSA.	The LPR bioassay results are a site-specific study in the NBSA system on growth and survival of polychaetes exposed to the COPECs (typically at higher concentrations than those in the Bay proper). This has been clarified in the text.		Response acceptable.	N/A

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119	6.3.1/ Appendix A	76	Comparison of the COPEC sediment chemistry between the 30 sampled stations and other Newark Bay surface sediment chemistry data would provide some insight into the degree of similarity between these two subsets of samples. The 30 SQT samples represent one sample for every 135 acres of the nearly 4,000-acre NBSA and additional comparative analysis would help the reader understand how representative these 30 samples are of the Phase III dataset. Please provide a set of appendix tables that compare basic statistical metrics for the two datasets (including number of samples, min/max of detected concentrations, average and standard deviation or CV) for all COPECs. In addition, please consider including probability plots (Q-Q or similar) to compare chemistry for the 30 reference stations to data for the NBSA generally (2 empirical distributions per graph) and the Jamaica Bay stations used in estimating the reference envelope. This could be done for the geomorphic sub-regions as well. The graphs could be created for selected COPECs and other sediment constituents (TOC, % sand, etc.), sum of toxic units, and mPECQs. Statistical tests of the similarity of the empirical distributions (e.g., K-S tests of significance) could also support this assessment. The results of the evaluations should then be discussed in Section 6.3.	A table comparing the SQT samples to the remainder of the Phase III sediment data set has been added to Appendix A (Table A-3-3) and the findings are summarized in Section 6.3.1 (now 6.4.1) and Appendix A (Section 4.1). Q-Q plots comparing the 30 SQT samples and the 59 Jamaica Bay reference samples for select chemicals used in the screening of Jamaica Bay data were prepared and are included in Attachment A-1 of Appendix A. The Q-Q plots show that the chemical concentrations in the SQT samples are elevated compared to the Jamaica Bay reference. Also, a comparison of all 2008 and 2013 Jamaica Bay data versus the entire Phase III sediment chemistry data set is discussed in Section 4.4.2 of the BERA (see also Table 4-12 of the BERA).	Please provide statistical summary tables for the entire Phase III and SQT datasets as requested in the original comment. For select chemical parameters (see recommendations for Comment #21 above), EPA believes that either probability plots or box plots (for the entire NBSA as well as north, southeast and southwest subareas) would be useful in promoting reader understanding of the representativeness of the SQT dataset.	Response acceptable (Table 4-12 reference in response should be Table 4-14); however, it would be worth pointing out that mean and median TOC concentrations in the SQT set are approximately 50 and 30 percent higher than corresponding statistics in the Phase III sediment dataset. The exposure implications related to extrapolating SQT-related conclusions to the larger dataset should be discussed.	The comment is correct, Table 4-14 should have been referenced in the response. The differences in TOC and percent fines for the two data sets are discussed in Section 6.4.1 of the revised BERA and Section 4.1 of Appendix A.
120	6.3.1	76	5th paragraph. See Comment No. 183.	See response to Comment 183.		Response acceptable.	N/A
121	6.3.1	76	Please provide additional details regarding the sensitivity evaluation of the 2013 REMAP dataset in deriving the reference envelope for the SQT analysis. Although Appendix A Section 4.1 (page 29) briefly discusses the reanalysis of the Jamaica Bay data set	The revised reference envelope calculations excluding the 2013 samples are in Attachment 1 of Appendix A (Table A-1-1).		Response acceptable.	N/A

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			without the 2013 REMAP data – resulting in no effect on the NBSA SQT evaluation – the data/results of this reanalysis do not appear to be included in Appendix A.				
122	6.3.1	77	1st paragraph. Please provide details to support the statement "nor was there a change in chemical concentrations when 2008 and 2013 are compared".	This sentence was reworded to say: "The mean chemical concentrations presented in Appendix A are similar between the two programs." The summary statistics for the two programs are now presented in Appendix A (Table A-1-5).		Response acceptable.	N/A
123	6.3.1	77	1st paragraph. Although BIC metrics currently don't indicate impacts relative to Jamaica Bay, please include a more complete analysis of the historical dataset in the discussion; particularly the relationship between historical chemistry and both laboratory and community data. A demonstration of trends in improved exposure conditions and biological response would make the analysis more compelling. Also, there is no discussion of the potential impacts of using a different species of amphipod in the 2015 data, although this is described in Appendix D. Please add that information to the text. There is some *Leptocheirus* data for Jamaica Bay and a single *Leptocheirus* SQT sample collected in Newark Bay in 2010 that could be considered along with a summary of the comparative studies of *Ampelisca* and *Leptocheirus* toxicity.	A discussion of the correlation analyses of the historical REMAP data (Table A-32 of Appendix A) has been added to Section 3 of Appendix A showing that correlations between acute toxicity, BIC metrics and sediment chemistry have been demonstrated in past studies. This analysis is also discussed in Section 4.1 of Appendix A and Section 6.3 of the BERA. The discussion of historical data also shows the decline in the proportion of toxic samples in the NBSA over time as demonstrated by these historical studies (see Section 3.4 of Appendix A). The raw REMAP data (chemistry, toxicity and BIC) collected in the NBSA has been added as Attachment A-6 to Appendix A. Both A. abdita and L. plumulosus were found to be comparable in their ability to classify sediment samples as toxic in an inter-species and interlaboratory study conducted by Schlekat et al. (1995). This was discussed in Section 2.3.3 of Appendix A and is now also cited in the uncertainty section of the BERA (6.4.1) and Appendix A (4.1) and in Section 6.1.1.2 of the BERA.	See Comment #105. EPA believes that reader understanding could be improved by inclusion of figures (e.g., box plots) showing trends in 10-day toxicity, selected BIC metrics (e.g., taxa richness and Shannon-Weiner diversity) and SQT scores for both Newark Bay and Jamaica Bay since the 1993-1994 REMAP sampling event. Comparison of these trends with those of key potential chemical stressors (see Table A-21) would be also be useful. In addition, please include a discussion of what is known about the relative sensitivities of Leptocheirus and Ampelisca to the principal NBSA COPECs in the appropriate uncertainty discussion.	Response acceptable.	N/A

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124	6.3	77	See Comment No. 119. Please provide any information on any sampling method differences (e.g., sieve size, mesh size, depth of sediment sample collection); differences in methods may significantly affect abundance and species richness, as well as other indices. Also, please discuss the consequences of low statistical power on the ability to detect statistical significance relative to the control in the toxicity tests. Please review the original assumptions about variability in the bioassay endpoint results used to support the number of SQT samples and estimate the minimum detectable differences (MDDs) for the individual bioassay endpoints. This evaluation and that suggested in Comment No. 183 would help readers understand the impact of variability on the analysis.	The text was revised in Section 6.4.1 of the BERA and in Section 4.1 of Appendix A to note the uncertainty due to the difference in sampling depths of the two programs, 2cm for REMAP and 6 inches for the NBSA. Sieve sizes were similar. The MDDs were calculated for the bioassay results and are provided in Attachment A-2 of Appendix A. The uncertainty due to statistical significance was evaluated as requested in Comment 183 and discussed in Section 6.4.1 of the BERA and in Section 4.1 of Appendix A.		Please see Comment #21.	See response to Comment 21.
125	6.3.2	77	Last paragraph. Please acknowledge the contravening uncertainty associated with the use of TRVs based on mortality in lieu of other sensitive endpoints that could also be of population consequence. This is particularly the case for COPECs for which early life stages are known to be particularly sensitive. Highlighting the TCDD invertebrate oyster TRV uncertainties without these leads to a biased analysis that doesn't adequately support decision making for the Site. As indicated, there is relatively little tissue residue data for invertebrates; however, the selection of a (freshwater) crustacean study based on a survival endpoint that was determined to be acutely lethal to test organisms (causing 50-66% mortality) as a TRV may very well not be protective of this assessment endpoint. The study confirmed that TCDD induced the cytochrome P450 system in this species; similar	See response to Comment 114.		See Comment #114.	See response to Comment 114.

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			inductions in other animals have been associated with a wide variety of adverse effects on various biological systems. It would be surprising that more subtle effects would not be found (as was the case with the oyster studies) if additional studies in this species or other crustaceans were conducted. See Comment No. 3.				
126	6.4, Table 6-21	78	Please explain the criteria used to assign risk categories and how they should be interpreted. What are the criteria for determining whether risks are "possible" or "unlikely"? Please refer to Comment No. 6. How are results of the LPR FFS TRVs evaluated in in these assignments, as it appears they were not included in the case of the blue crab tissue LOE? Ultimately these categories should relate to the population- and community level bases of the assessment endpoints, so interpretation of "localized risk" should also be clarified. Please expand the discussion accordingly.	Additional text has been added to Section 6.4 (now 6.5) to clarify the use of the risk classifications and describe how they can be interpreted. Also Table 6-21 has been expanded to better explain the basis of the risk classification.		Revisions based on this response improve the linkage between the risk assessment and risk management phases; however, please ensure that the TRV uncertainties discussed in Appendix D are summarized in Sections 6.4 and 6.5. For example, limitations of the tissue TRV for crabs (based on mortality) should be referenced when drawing conclusions about the magnitude of the tissue-based HQs.	The uncertainties section (6.5) has been updated accordingly to reflect the key uncertainties in the TRVs.
127	6.4	78	2nd paragraph. Please revise the first sentence to clarify that LOAEL-based HQs > 1 were observed for total DDx, dieldrin, and various metals for blue crab, and for total HMW PAHs and various metals for softshell clam; NOAEL-based HQs > 1 were observed for multiple COPECs for both organisms (Table 6-20, page 73).	This information has been added to the text and also to Table 6-21 describing the weight of evidence.		See Comment #175 regarding the WOE analysis and identification of preliminary COCs.	See response to comment 175.
128	6.4	79	This section states "[t]he overall risks to the benthic community based on sediment toxicity test results and exposure-response models from the SQT appear to be a function of localized elevated concentrations of multiple co-occurring COPECs"; concentrations of these COPECs at such locations appears to be "at or above the 90th percentile of the NBSA-wide concentration range in surface sediments" (Section 11.1, page 156). However, the elevated LPR LOAEL HQs	See response to Comments 116 and 118. Bioaccumulation in polychaetes is acknowledged as a secondary line of evidence for benthic risk. However, it is also noted in Section 6.2.3 that polychaetes have not been shown to be sensitive to COPECs in the LPR and NBSA system.		See Comment #175 regarding the WOE analysis and identification of preliminary COCs.	See response to comment 175.

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			for 2,3,7,8-TCDD (9) and total PCBs (2) in polychaetes (Table 11a, e-page 541) suggest these two (2) COPECs may be of particular concern to the benthic invertebrate community. Also see Comment No. 89 regarding 4,4'-DDT and revise accordingly.				
129	7	80	Aren't the fish community data considered to be a LOE for the fish assessment? Please add a description to this section.	Fish community data have been added as a formal LOI to the fish assessment in Sections 7 and 11.	See Comment #4. During the July 29th discussion, Arcadis agreed to include a discussion of the available fish community data.	Response acceptable.	N/A
130	7.1.2	81	See Comment Nos. 3 and 7. The LOAEL TRV of 300 ng/kg for dioxin (2,3,7,8-TCDD and dioxin TEQ) used in the fish assessment is quite high (relative to other available benchmarks) and is based on a growth endpoint from one mummichog study. In addition, mummichog are not considered to be a sensitive fish species and consequently, this value may not be protective of other components of the NBSA fish community. This is the type of information that should be included in the toxicity profiles presented in Appendix D to counterbalance the discussion on FFS value uncertainties.	The following information was added to Appendix D and Section 7.6.1 in response to this comment: "both of the sets of tissue TRVs are based on single studies using mummichog as a test species. While mummichog are resident to Newark Bay, and thus directly relevant, they may not be among the most sensitive species marine species. For comparison, the TCDD TRVs for freshwater fish derived in the LPRSA BERA (Windward 2019) are based on an SSD for seven species. The 5th percentile SSD value selected as the LOAEL TRV for the LPRSA BERA is the same as the NOAEL concentration (0.00012 mg/kg ww) reported in Salomon (1994). The NBSA LOAEL TRV of 0.0003 mg/kg ww corresponds with approximately the 12th percentile in the LPRSA BERA SSD and is lower than effect levels included in the LPRSA BERA SSD for sensitive species such as rainbow trout. Thus, use of the NBSA LOAEL TRV, 0.0003 mg/kg ww based on mummichog data (Salomon 1994), is not expected to substantially underestimate toxicity to other marine species. The LPRSA BERA LOAEL TRV and NBSA LOAEL TRV are both approximately two orders of magnitude higher than the LOAEL TRV developed for the LPR FFS (USEPA 2014). In the absence of toxicity data for marine species other than mummichog, it is presumed that TRVs derived for the NBSA are adequately protective of other potentially more sensitive fish species."		To be reevaluated following review of revised Appendix D.	The 2,3,7,8-TCDD TRV for fish tissue has been revised to the values used in the LPR OU4 BERA.

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131	7.1.2	82	3rd paragraph, last sentence. Please delete this sentence.	The sentence has been deleted.		Response acceptable.	N/A
132	7.1.3.2	87	Last paragraph. The statement "Similarly, while the zinc No Observed Adverse Effects Concentration (NOAEC) HQs are > 1, the fact that zinc did not exceed any of its NOAEL or LOAEL HQs in a whole-body sample of any fish species evaluated clearly indicates that is does not pose a risk" seems to short-circuit the deliberative Weight of Evidence (WOE) evaluation of different LOE. Please revise to focus on the different conclusions suggested by the two LOE.	The following text was added to the report in Section 7.2.3.2: "while the zinc NOAEC liver HQs are > 1, there is uncertainty associated with both the exposure and effects assumptions. The liver datasets are smaller than for whole body tissue; only the NBSA-wide liver EPC is based on a 95UCL, as the assessment zones had too few samples to calculate this statistic. Additionally, there is a high degree of uncertainty in the interpretation of liver HQs to effects in whole fish and fish populations. Specifically for zinc, fish actively regulate the uptake and distribution of this essential metal (Bury et al. 2003) and tissue burdens vary widely between species (USEPA 2007b). Although there is uncertainty in the use of tissue HQs for metals, the whole-body TRVs are considered to be less uncertain for estimating risk to individuals and fish populations than liver TRVs. The fact that zinc did not exceed any of its NOAEL or LOAEL HQs in whole-body sample of any fish species evaluated indicates that it does not pose a risk."		Response acceptable.	N/A
133	7.2.1.1	88	Please check the units in Equation 7-1 as it doesn't appear that the Exposure Point Concentration (EPC) terms should be expressed on a body-weight normalized basis if the ingestion rate term is expressed as food intake per kg receptor body weight per day.	The units have been corrected.		Response acceptable.	N/A
134	7.2.1.2, Table 7-6	89	The ingestion rate terms in Table 7-6 are not body weight-normalized and a footnote to clarify the distinction between the Ingestion Rates (FIR/SIR and the IR$_x$ terms) would be helpful.	For consistency, the equation has been revised to express the ingestion rates on a non-normalized basis similar to the way they are expressed in the table.		Response acceptable.	N/A

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135	7.2.1.2	89	Molluscs comprise a substantial percentage of the macroinvertebrate biomass in the NBSA and yet are not assumed to be a dietary component of any of the modeled fish species. What is the rationale for this omission?	Fish diets were updated to include macroinvertebrate biomass: Summer/winter flounder = 25% worm, 25% blue crab, 25% softshell clam, and 25% fish ≤ 30 cm White perch diet = 40% worm, 20% crab, 20% clam, 20% fish <15 cm American eel <50 cm diet = 40% worm, 20% crab, 20% clam, 20% fish <15 cm American eel ≥ 50 cm diet = 20% worm, 20% crab, 20% clam, 40% fish ≤ 30 cm		The revised fish diets appear reasonable and address the comment; however, please correct the revised table (now 7-10), which incorrectly indicates that clams represent 50% of the summer/winter flounder diet. Also suggest revising "Proposed NBSA BERA Diet" to just "NBSA BERA Diet". Please see Comment #197 regarding integrating the results of the sensitivity assessments into the risk summaries.	The flounder % clam in the diet was corrected in Table 7-10. The results of the sensitivity analyses are described in detail in the Uncertainty Sections. Additional preliminary COPECs identified as a result of the sensitivity analyses are summarized in the text and have been added to the existing TRV exceedance tables for fish (Tables 7-20, 7-21, 7-22, 7-23, and Section 7-7), birds (Tables 8-11, 8-12, 8-13, 8-14 and Section 8-4) and mammals (Table 9-5, 9-6, 9-7, 9-8 and Section 9-3).
136	7.2.2	91	Please provide backup calculations for the fish diet TRVs for lead and silver as neither could be verified.	Further detail on the lead and silver TRVs was provided to the EPA in July 2019.		Response acceptable; however, please check supplemental comments on TRVs recently provided to GSH.	See response to supplemental Appendix D comments 187 - 253 below.

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137	7.3	92	Please add text to explain why only *Fundulus* species were selected for the fish egg assessment; presumably it is because they are resident species. Based on previous USACE ichthyoplankton sampling there are other species spawning in NBSA – most notably winter flounder – which are an EFH species of concern. Please address whether egg exposure calculations (weighted by time spent in NBSA for the spawning adults) should be included.	As directed by the USEPA in comments received on the Arcadis EF/TRV Technical Memorandum, the fish egg assessment was conducted in a comparable manner to that of the LPRSA BERA. Only Fundulus sp., a resident species in the LPRSA and NBSA, was assessed. This is a conservative assessment of potential egg bioaccumulation, as this species is exposed to Bay sediments year-round. No additional analyses or text edits were added to BERA to address this comment.		EPA disagrees that the egg modeling of forage fish necessarily results in a conservative assessment of this endpoint as higher trophic level fish species have higher tissue concentrations of bioaccumulating compounds. Although consideration of non-resident species introduces uncertainty regarding the relative contribution of NBSA contamination to the exposure assessment of migratory fish, a sensitivity analysis should be conducted to support the contention that the egg modeling analysis is in fact conservative. Another consideration is that the potential impact of dioxin and other COPEC exposures on non-resident species may be more consequential because the populations are less likely to be adapted to local contaminant exposures. Table 1 summarizes KM-mean and 95%UCL TCDD concentrations in Fundulus and white perch (Tables C-9 and C-10 in the revised BERA). Concentrations in white perch (juveniles or adults?) are up to 3 times higher than Fundulus. In addition, the draft NBSA bioaccumulation model predicts that between 50-60% of the total body burden in white perch captured in the NB north area is derived from NBSA-specific exposures. The sensitivity analysis should evaluate these differences in comparison to the estimated Fundulus egg risks presented in Table 7-15.	The language in the fish egg uncertainty assessment has been revised to include perspectives on possible species differences. No further assessment of fish eggs for other species is evaluated. The original direction from the USEPA was to add a fish egg assessment using the same approach and information from the LPRSA OU4 BERA. The LPRSA BERA only collected data to conduct a fish egg assessment for resident *Fundulus* sp. No egg data for other species were collected or assessed, nor were sensitivity analyses conducted for other species, despite their presence in the system. Therefore, the egg assessment for the NBSA is limited to *Fundulus* sp. and perspectives on potential higher concentrations in other species are provided in the uncertainty analysis.
138	7.3.1.3	93	EPA was unable to verify the egg tissue EPC calculations; please provide calculation details including lipid levels and wet weight/dry weight conversion assumptions.	Supplemental explanatory tables that show fish egg EPC calculations were developed and included in Appendix C.		Response acceptable.	N/A
139	7.3.2	93	Please correct reference to fish egg TRVs. Also, is the footnote 4 reference to UCL statistics intended to be for Appendix C-7 rather than Appendix C-1?	The reference to fish egg TRVs has been corrected. The footnote has been corrected.		Please update the footnote reference to the fish egg UCL statistics (now in Table C-15, not C-7).	The footnote was updated to reference the correct table.

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140	7.5	95	3rd paragraph. While the sensitivity analyses that are presented are very helpful, further support for the conclusion that the risk estimates are likely overestimated should be provided. In general, it seems that the discussion of uncertainties throughout the BERA is biased towards those that are considered to result in risk being overestimated. Please provide a more complete accounting of the various types of uncertainties and, if possible, qualitatively classify each with respect to likely direction of effect and degree of impact on the risk conclusions. Other factors that should be considered include the representativeness of the 8 sediment samples used in the polychaete bioaccumulation test with respect to the Phase III sediment data set (both in terms of spatial coverage and contaminant exposures). Rather than assume 100% bioaccessibility, isn't the assumption that the contaminants are as bio assessable as in the studies that were the basis for the TRVs, such that the uncertainty is due to the relative bioaccessibility of laboratory feed versus natural diets?	The magnitude and direction of uncertainties was added to Section 7.5 (now Section 7.6 Uncertainties), where appropriate. Text was added to Section 7.6 (3rd paragraph) to clarify that bioaccessablity assumptions apply when HQs are based on dietary models extrapolated from sediment analytical data, and that there is uncertainty due to the relative bioaccessibility of laboratory feed versus natural diets. Uncertainties related to spatial representativeness of the polychaete worm tissue EPCs were added to Section 7.6.3.		Response acceptable.	N/A
141	7.5.1	97	The following uncertainties should be included in this section:			See below.	See below.
			1. The lipid content used in the fish egg assessment is based on a value derived for mummichog (3.3%), which may underestimate risk for other species.	Text has been added that the use of the 3.3% lipid value may result in over- or underestimation in the egg concentration of other species.		It would be helpful to provide a range of lipid concentrations in estuarine fish species and summarize the potential impact of this uncertainty on the risk findings.	A range of lipid concentrations from mid-Atlantic estuarine fish species was added to the text of Section 7.6.4 (Fish Egg Tissue Risk Characterization Uncertainties).
			2. The conversion factors of 0.6 and 1 from whole body to egg may underestimate risk. Egg to whole body ratios in mature gravid female fish may be greater than 1 for some species.	For the NBSA BERA, CFs identified in the final USEPA-approved LPRSA BERA were used for the fish egg risk assessment. The LPRSA BERA concluded that use of a CF of 1 for mercury/methylmercury likely overestimates risk to fish eggs.		Response acceptable.	N/A

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142	7.5.2.1	98	1st paragraph. The statement regarding the relative importance of water-soluble fractions is not necessarily consistent with the bioaccumulation model being developed for the NBSA, so some clarification (supported with literature references) should be added. In addition, most natural systems and particularly estuaries are in a state of disequilibrium operating over scales ranging from daily (tidal cycles) to years (episodic storm events). Please clarify the discussion.	This statement has been removed from the discussion to avoid any confusion, or draw conclusions that are being evaluated on a site-specific basis for the NBSA as part of the bioaccumulation model development.		Response acceptable.	N/A
143	7.5.2.1	98	Please include a discussion of the potential adverse effects of PAH metabolites on fish early life stages (Barron et al 2004; Incardona et al., 2005).	This discussion has been added.		Response acceptable.	N/A
144	7.5.3	100	Juvenile fish utilize nearshore areas in the late spring to summer. Because minnow traps and seines - two fishing techniques that would capture small fish - were only used in the October 2014 sampling event, the investigation does not properly characterize juvenile fish use of the nearshore areas within the NBSA. Trawls and gillnets are selective sampling gear that mostly sample larger fish or small fish residing on the bottom in subtidal areas. In addition, the historical NBSA ichthyoplankton dataset is not robust enough to evaluate the potential for early-life stage effects attributable to the COPECs, particular emphasis on dioxin/furans and PCBs on the fish community. Please discuss these data limitations along with the uncertainties associated with the fish egg modeling LOE.	This comment has been addressed. Text has been added to Section 7.6.1 regarding fish sampling gear-related uncertainties. More importantly, however, the new fish community LOI is discussed in Sections 7.1.1 and 7.6.1 and provides more perspective on findings from historical multi-year adult/juvenile and ichthyoplankton surveys conducted in the NBSA and contrasted to comparable data from other regions in the NY/NJ Harbor Estuary, as well as literature for mid-Atlantic estuaries. Between the site-specific and historical surveys, it is likely that potential juvenile and adult fish use of the various areas of the Bay is well characterized and properly accounted for in the BERA. The sensitivity of fish to such compounds as dioxins/furans and PCBs is captured in the tissue assessments and conservative mummichog (resident intertidal fish species) egg modeling.		Please see Comment #137 (re: degree of conservatism of Fundulus egg model) and Comment #43 (heuristic value of the ABS dataset).	See responses to Comments 137 and 43.
145	7.6	101	Please present conclusions based on both the NBSA and LPR FFS TRVs and revise Table 7-20 accordingly.	Table 7-20 (now 7-24) has been completely revised and presents conclusions based on both sets of TRVs.		This table (and parallel tables in Sections 8 and 9) is still not consistent with EPA direction or with the risk summaries in the Final OU4 BERA and needs to be revised. See Comment #175.	See responses to Comments 3 and 175.

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146	Table 7-15	102	Please clarify the criteria used to categorize "reliability" and discuss the classifications from the perspective of bounding the risk estimates. The LPR FFS values are acknowledged to be more conservative than the corresponding values developed by the CPG. Their intent is to benchmark effects to more sensitive endpoint receptors belonging to a particular trophic category. They are thus considered to be more reliable for estimating risks for this purpose. The reliability estimates provided in the table are more appropriate when considering less sensitive members.	The text in Section 7.7 has been revised to explain the criteria used to estimate reliability classifications given in Table 7-19 (formerly Table 7-15).		Response acceptable.	N/A
147	Table 7-15	102	Please review the use of risk modifiers in the table after addressing comments on Appendix D (Toxicity Profiles).	The reliability classifications in Table 7-19 (formerly Table 7-15) were reviewed and updated as appropriate based on the information in Appendix D, underlying toxicity datasets, and specific uncertainties (e.g., consideration of nutritional thresholds, background concentrations).		To be reevaluated following review of revised Appendix D.	Table 7-19 has been removed from the BERA.
148	7.6.1	104	Please revise the conclusions after addressing Comment No. 147 and ensure that risks associated with the LPR FFS TRVs are included. Same comment for subsequent subsections.	See response to Comment 145.		Response acceptable.	N/A
149	7.6.5	111	Revise once the comments on the individual fish receptors have been addressed.	This comment has been addressed.		Response acceptable; however, see Comment #145 regarding the WOE analysis and identification of preliminary COCs.	See responses to Comments 3 and 175.
150	8	114	3rd paragraph. Please correct "Risk Questions 1" (change to singular).	The correction has been made.		Response acceptable; however, please also correct references to AE and RQ in the second paragraph which should also be singular.	References to AE and RQ have been edited as requested.
151	8.1.1.1	115	Please refer to Comment No. 133 regarding units for the EPC terms in Equation 8-1.	The units for the EPC term have been corrected.		Response acceptable.	N/A

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152	8.1.1.2/ Table 8-1	115	Although consistent with the EPA-approved NBSA BERA recommended exposure factors memorandum (Arcadis, 2016), the lesser scaup do not typically include fish in their diet due to beak morphological constraints. Please evaluate the impact of including fish in the diet of the lesser scaup and summarize conclusions in Table 8-8.	The following alternative lesser scaup diets were evaluated in the sensitivity analyses (Appendix F): A: 25% crab; 25% clam; 50% worm B: 25% crab; 50% clam; 25% worm C: 75% clam; 25% worm The results are discussed in the uncertainty section (8.3.1.2.4).		Response acceptable; however, please integrate results (summarized in Table F-7-1 through F-7-3) into the summary. Overall summaries need to include FFS LOAEL HQs >1 and also identify alternative scenarios that meet the criterion for identification as preliminary COCs.	See responses to Comments 3 and 175. The results of the sensitivity analyses have been added to the TRV exceedance tables for each receptor in Section 8. The results of sensitivity analyses have been added to the TRV exceedance tables in Sections 7 and 9 as well.
153	8.1.1.2	116	Consistent with the 17-mile BERA, please conduct a sensitivity analysis for the heron using various percentages (e.g., 5%, 10% and 100%) of fish > 30 cm included in its diet and summarize findings in Section 8.3.	The following alternative great blue heron diets were evaluated in the sensitivity analyses (Appendix F): A: 100% fish > 30 cm B: 10% clam; 10% crab; 75% fish ≤ 15 cm; 5% fish > 30 cm C: 10% clam; 10% clam; 70% fish ≤ 15 cm; 10% fish > 30 cm The results are discussed in the uncertainty section (8.3.1.2.5).		Response acceptable; however, please integrate results into the summary. Overall summaries need to include FFS LOAEL HQs >1 and also identify alternatives that also have these results. Results are summarized in Table F-6-1 through F-6-3.	See responses to Comments 3 and 175. The results of the sensitivity analyses have been added to the TRV exceedance tables for each receptor in Section 8. The results of sensitivity analyses have been added to the TRV exceedance tables in Sections 7 and 9 as well.
154	8.1.1.3	117	Please provide additional details on exposure assumptions for the various assessment zones/habitats.	See response to Comment 9. A list of all sediment and biota samples and the assigned exposure area have been added to Section 4.		Response acceptable.	N/A
155	8.1.1.4	117	Please provide backup calculations for the bird diet TRVs for arsenic, dieldrin, total chlordane and hexachlorobenzene as these could not be verified.	This information was provided to the USEPA in July 2019.		Response acceptable.	N/A
156	8.2	120	3rd paragraph. Please clarify the following statement "*In addition, the COPECs analyzed in the study for which egg TRVs are not available were assessed in the context of the study findings with respect to the measured reproductive endpoints.*"	This comment has been addressed.		Response acceptable.	N/A
157	8.3.1.2.2	126	2nd paragraph. Please correct reference to Figure 8-2, which presents regression data for total PCBs, not 2,3,7,8-TCDD. Is there a similar regression analysis for TCDD?	Figure 8-2 has been corrected and now shows the regression for 2,3,7,8-TCDD.		Response acceptable.	N/A
158	8.3.2	128	3rd bullet. Please note though that multiple contaminant exposures and site foraging fidelity both contribute uncertainty to the interpretation of the Parsons study findings.	These considerations have been added.		Response acceptable.	N/A

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159	8.4	130	3rd paragraph. Please caveat this conclusion by indicating that the findings may have been biased by the predation.	This caveat has been added.		Response acceptable.	N/A
160	8.4.5	136	Please revise the avian risk findings as necessary based on responses to the comments on this section.	This comment has been addressed.		The section has been updated with the alternative scenario analysis; however, please revise so the range of LOAEL HQ>1 (based on NBSA and FFS TRVs) are advanced to the FS.	See response to Comment 3 and 175
161	8.4.5	136	Revise discussion to present risk conclusions based on the FFS TRVs.	The text has been revised in Sections 8.4.1 through 8.4.5 to add a discussion of FFS TRV results where necessary.		Response acceptable; however, please see Comment #175 regarding the WOE analysis and identification of preliminary COCs.	See response to Comment 3 and 175
162	9.1.1.1	139	See Comment No. 133 regarding units for the EPC terms in Equation 9-1.	The equation and units have been corrected.		Response acceptable.	N/A
163	Table 9-5	143	Please change column headers to "NBSA and LPR FFS HQs ≥ 1.0" as information based on both exceedances of NOAEL and LOAEL TRVs are presented.	This comment has been addressed.		Response acceptable.	N/A
164	Figure 9-1	144	Please include the risk results based on the LPR FFS values.	The figure has been revised to included LPR FFS values.		Response acceptable.	N/A
165	9.2.1	146	3rd paragraph. EPA is currently conducting a review of the mink TRVs that were used and will provide an update to GSH as part of the comment discussion process.	This comment is acknowledged.	The mink TRVs for PCBs that were used in the Newark Bay BERA were all derived from the Chapman 2003 paper, are consistent with the BERA that was completed for the Lower Passaic River Study Area, and are valid for evaluating ecological risk to mink. The Hudson River five-year review that was recently completed included an extensive literature review for PCB mink TRVs. The review indicated that the most relevant TRV for PCB exposure in mink was based on the Bursian et. al, 2013 paper. A discussion of this paper (Bursian) should be included in the uncertainty section to provide an additional upper-bound NOAEL and LOAEL risk estimate [0.0033 mg/kg/day (NOAEL) and 0.033 mg/kg/day (LOAEL)]. Bursian, S. J., et al. (2013). "Dietary exposure of mink (Mustela vison) to fish from the upper Hudson River, New York, USA: Effects on reproduction and offspring growth	Response acceptable.	A discussion of the Bursian et al. (2013) paper is included in Section 3.4.3 of Appendix D. Given that this value was derived post-LPRSA BERA and is not being used in the risk calculations for the NBSA BERA, it was not discussed in the main text. The uncertainties section refers to Appendix D for such discussions.

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					and mortality." Environ. Toxicol. Chem. 32(4): 780-793.		
166	9.2.1	146	4th paragraph. The mink TCDD TRV is another example of an apparent bias in the discussion of uncertainties. The fact that the Tillitt study is based on multiple contaminant exposures is appealing in the sense that synergistic effects among different chemical categories is also a concern for the NBSA. See Comment No. 3 and after revising Appendix D, please revise to provide a more balanced discussion of the pros/cons associated with the two study diets.	A discussion of this issue has been added to Appendix D (Section 2.4.2), and Section 9.2.1 of the BERA.		To be reevaluated following revisions based on the supplemental comments. The issue is that the WOE integration advances this same problem of bias.	See responses to Comments 3 and 175. See response to supplemental Appendix D comments 187 - 253 below.
167	9.2.1	146	Please provide backup calculations for the mammal diet TRVs for chromium , silver , 2,3,7,8-TCDD , total DDx , total chlordane and hexachlorobenzene as these could not be verified.	The requested information was provided to the USEPA in July 2019.		Response acceptable.	N/A
168	9.2.2	147	Please discuss the specific exposure assumptions for the muskrat (shoreline exposure) and prey foraging assumptions.	This comment has been addressed. Muskrat exposure was revised to include all shoreline sediment samples for the incidental sediment ingestion and plant (based on sediment to plant BAFs) portions of their diet. The samples included in the assessment are listed in Tables 4-10 and 4-11.		Response acceptable.	N/A
169	9.2.2.2	148	Please refer to Comment No. 157 regarding the total PCB regression presented in Table 8-2. Also, please include the following before the last sentence (or footnote): This is not unexpected given the relatively small dietary exposure attributable to invertebrates in the mink diet. It should also be noted that the regression analysis assumed that the sediments used in the laboratory bioaccumulation study are representative of conditions throughout the NBSA (see Comment No. 133).	Figure 8-2 has been corrected. The sentence has been added.		Response acceptable.	N/A

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170	9.2.2.4	149	Consistent with the 17-mile BERA, please conduct a sensitivity analysis for the river otter using various percentages (e.g., 5%, 10% and 100%) of fish > 30 cms included in its diet and summarize findings in this section.	The otter diet evaluated in the BERA is 5% worm, 5% crab, 10% clam, and 80% fish ≤ 30 cm. The following alternative river otter diets were evaluated in the sensitivity analyses (Appendix F): A: 100% fish > 30 cm B: 5% worm; 10% clam; 5% crab; 70% fish ≤ 30 cm; 10% fish > 30 cm C: 5% worm; 10% clam; 5% crab; 75% fish ≤ 30 cm; 5% fish > 30 cm		Response acceptable.	N/A
171	Table 9-4b	-	Please check and provide details for the muskrat HQs for total dioxin/furan/PCB TEQ mammal calculations, as these values could not be verified.	EPC calculations for all dietary inputs are provided in Appendix C. The food web model calculations for all constituents and all receptors are provided in Appendix E.		There appears to be a problem with calculation of the plant EPCs and muskrat risk calculations. None of the related calculations in the Appendix E tables could be corroborated. For example, D/F/PCB TEQ calculation as ratio of plant and sediment EPCs is 0.0019 (Table E-2-2; 2.3E-07/1.2E-04) but the BAF in Table 9-2 is 0.0056. In addition, various soil to plant regression models identified in Table 9-2 that were obtained from USEPA, 2007 are based on natural logarithms; however, it appears that the calculations used in the dose modeling summarized in Appendix E used log10. This results in the plant consumption dose estimates being under-estimated (by factors of approximately 2 in the two cases evaluated). Please check and revise Appendix E and dependent text and tables as necessary.	Sediment data was in dry weight. All tissue data is in wet weight. We assumed 80% moisture to adjust the BAF-derived plant tissue to wet weight. A footnote was added to the tables in Appendix E and discussed in the text Section 9-1.
172	9.3.4	151	See Comment No. 5. Please provide a perspective on future ecological exposures and potential risks in the NBSA. EPA will be interested in understanding whether the BERA findings are adequate and sufficient to support decision-making and the rationale for not estimating future risks in the document should be summarized.	See response to Comment 5.		Response acceptable.	N/A

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173	10.2	153-154	Please provide additional justification for the determination that uncertainty in the reptile assessment is assumed to be low considering the lack of toxicological data, the documented reproductive effects of PCB burdens in some reptiles, and the fact that the terrapin is a watch list species for the state of NJ and an individual focus (rather than a population focus) may be appropriate.	GSH believes the basis for this conclusion is sound. The likelihood of exposure for terrapins in the Bay is low, and surface water (which has negligible concentrations of COPECs) would be a primary exposure route. In addition, the sensitivities of these organisms to PCBs reported in the scientific literature is not as high as those for mammals. Given the lack of risk for mammals, it is reasonable to conclude a low potential for risk to terrapins/reptiles.		Response acceptable.	N/A
174	11	155	Please revise once comments on individual AEs have been addressed.	The BERA has been revised to address all prior individual comments related to AEs and MEs.		Response acceptable.	N/A
175	11.1	155	Please add further discussion of how the adequacy and strength of LOEs were determined with consideration of the requirement that the risk analysis characterize the potential range of risks to receptors.	Text was added referring the reader to Section 3.5.3, which describes the weight of evidence approach.		Per direction from USEPA and consistent with the OU4 BERA, preliminary COCs should include all LOAEL HQs >1. While concerns related to the FFS values are important for EPA to consider, the contravening issues with the NBSA TRVs are not similarly discussed. The WOE approach should be revised after addressing the supplemental comments on Appendix D and revising the presentation of supporting LOE (including fish community, fish pathology and bird egg studies) and revising the WOE findings in Sections 7, 8 and 9. Consistent with the process anticipated for OU4, further consideration of the relative merits of the various LOEs will be addressed in the FS.	See also responses to Comments 3 and to supplemental Appendix D comments 187 - 253 below.
176	11.1	156	Item 3. The term "uncertain" seems inappropriate as there is uncertainty associated with other categories as well. Please consider using a different term. In addition, the BERA planning phase should have led to the collection of sufficient information to make definitive conclusions. Why are LOEs considered "insufficient"?	While sufficient data were collected to evaluate ecological receptor exposures in the NBSA, toxicity data used to evaluate the exposures was selected primarily from published literature. Toxicity data for some receptors are limited. This has been clarified in the text.		Response acceptable.	N/A

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177	11.1	156	3rd paragraph. The broad statement that "the vast majority of the sediments throughout the NBSA are nontoxic and pose no risk to benthic communities" (pg. 156) is not supported by the data. Refer to Comment No. 124 regarding statistical power and qualify this statement with the observation that two-thirds of the sediment toxicity samples had survival less than 80% of control or growth less than 70% of control.	The statement is based on the modeling evaluation and the areas of predicted toxicity shown in Figures 6-6 and 6-8, which are now cited. This paragraph has also been revised to include more specific information on the toxicity results.		The expression "vast majority" is still misleading as 46 out of 244 (~20%) non-nav channel Phase III stations are predicted to result in chronic toxicity (<60 and between <80 and >60 percent of control). Please revise.	The term "vast majority" has been changed to "majority."
178	11.2	157	The following statement should be removed from the list of conservative practices and assumptions used: "Reproductive, developmental, and mortality effects, among the most sensitive of test endpoints for evaluating effects at the individual and population-level, were the preferred endpoints when identifying toxicity studies used in the selection of TRVs" (second bullet, pg. 157). These endpoints are the most appropriate endpoints for assessing individual or population level effects and are not "conservative."	This comment has been addressed.		Response acceptable.	N/A
179	11.3/ referenced tables	157	Please update list after addressing Comment No. 7 as all COPECs that exceed NOAEL- or LOAEL-based TRVs (both NBSA and FFS) should be included.	See responses to Comments 3 and 8.		Please refer to EPA responses to Comments #3 and #8.	See responses to Comments 3 and 8.
180	Appendix A		EPA conducted a review of the SQT analysis and found no substantive discrepancies with the scoring results presented in Appendix A and summarized in Section 6 of the BERA.	No action is necessary to address this comment.		Response acceptable.	N/A
181	Appendix A/ 2.1.3	4	See Comment No. 119 re: representativeness of the SQT dataset. Please conduct statistical comparisons and comparative box and/or Q-Q plots for physical characteristics (including % fines, salinity, total organic carbon and bottom dissolved oxygen levels, as available) for both the entire Jamaica Bay sediment dataset (along with the subset used to develop the reference	See response to Comment 119. A comparison of the physical characteristics (TOC and grain size) for Jamaica Bay and Newark Bay has been added as Table A-1-7 of Attachment A-1 of Appendix A. Salinity and dissolved oxygen data were not available for the REMAP data.	See Comment #119.	Response acceptable; however, please summarize comparative data on bottom dissolved DO and salinity (both included in the REMAP datasets). The potential implications of any substantial differences in these parameters should also be discussed if they exist.	Summary statistics for salinity and dissolved oxygen in bottom samples has been added to Table A-1-7 and discussed in Section 2.1.3 of Appendix A.

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			envelope) and compare the latter to conditions associated with the SQT and Phase III stations. Please update this section with a summary of this analysis.				
182	Appendix A/ 2.1.3	4	Please include a discussion of the difference in sampling depths for the JB and NBSA sediment chemistry data. The Jamaica Bay sediment samples were collected at a depth of 0-2 cm, which is different than the 0-15 cm depth to which the LPRSA SQT sediment samples were collected. This difference in sample depth increases the uncertainty of the results of the NBSA SQT evaluation.	The following sentence has been added to Section 2.1.3, "It should be noted that the SQT samples were collected at a depth of 0 to 15 cm while those in Jamaica Bay were collected at a depth of 0-2 cm, which adds some degree of uncertainty to the BIC comparison."		Response acceptable.	N/A
183	Appendix A	12	Please consider supplementing the approved SQT scoring with the following sensitivity evaluations that would help provide a more robust understanding: (1) The absence of statistical significance in the 28-day survival test for a number of samples with <80% of control (7 of 30 samples) indicates high variability in control and/or test samples. Including statistical significance and treating samples with as low as 46% survival (57% of control) and 6 other samples <80% of control as showing "no impact" (pg. 59 and Table 6-1) could inappropriately under-estimate the contaminant impacts and affect the SQT scoring. A more conservative approach would treat all samples with survival <80% of control as different from control. Please ensure that the impact of high control or test result variability is discussed in Appendix A and summarized in Section 6.3.	1) This alternative scoring was evaluated in Appendix A (Section 4.1 and Attachment A-5) and also summarized in Section 6.3.	(1) There was agreement on the July 29th call that a sensitivity evaluation of the impact of high control variability would be added to Appendix A and summarized in Section 6.3. (2) Please refer to Comment #97.	Response acceptable; however, please make sure that the conclusions of the alternative scoring evaluations are carried to the discussion of risk conclusions.	Discussion of the MDD for the 28-day survival endpoint and the number of stations that would be toxic based on a relaxed definition of toxicity (i.e., 28-day survival less than 80% of control regardless of statistical significance) has been added to the tables that summarize risk conclusions, Tables 6-17 and 11-1b. The impact on SQT scoring has also been added to these tables.

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			(2) The sediment chemistry/porewater assessment only addresses individual contaminants; the analysis should also include mixture models such as toxic unit models for PAHs and other organic contaminants, mPECQs (after MacDonald et al., 2000 - Consensus Guidelines) and probability of toxicity models. In particular, analysis should be performed to assess the toxicity of PAH mixtures. Using PAH toxic units (e.g., using the Target Lipid Model, TLM) is a well-accepted assessment approach and, for chemicals that exert non-specific additive toxicity by narcosis, would be a valuable part of the sensitivity analysis.	2) An evaluation of the PAH toxic units has been added to the BERA in Appendix A and is also described Section 6.1. The analysis was conducted as described in USEPA (2003) and in USEPA (2017; cited as Burkhard 2017 by the commenter). MacDonald et al. (2000) is not relevant to the NBSA as it presents freshwater sediment quality guidelines. If the intention of the statement was to suggest an ERM-quotient approach, please see response to Comment 97.		Response acceptable.	N/A
			These results should be carried forward and summarized in Section 6 as appropriate.	The results were carried forward and summarized in Section 6.		Response acceptable.	N/A
184	Appendix A/ Section 3.4	26	The last paragraph/sentence should be removed or revised as it is a misleading final statement. Although it is true that most of the benthic macroinvertebrate community metrics don't demonstrate chemical impact, they also don't demonstrate absence of chemical impact.	The sentence was revised as follows: "PC1 is a significant predictor of density (p=0.026; R2= 0.17); however, because density can either increase or decrease as a result of degradation (Weisberg et al. 1998), this relationship is not evidence of chemical impact to the BIC."		Response acceptable. N/A N/A N/A	N/A
185	Appendix A/ Section 4.1	27	The discussion of the relative uncertainties associated with the use of sediment and porewater COPEC concentrations to evaluate exposures should include consideration of the following:	1.The porewater analysis has been revised to include an evaluation of the PAH mixture in pore water as described in USEPA (2017; cited as Burkhard 2017 by the commenter).		Response acceptable.	N/A
			1. The porewater analysis relies on individual chemical comparisons without consideration of mixture effects for PAHs and other organic compounds which is recommended by Burkhard et al. (2017).			N/A	N/A
			2. The description of the sediment tests as exhibiting a "low level of observed toxicity" ignores the fact that 12 of 30 samples had 28-day survival less than 80% of control and another 8 samples had 28-day growth less 70% of	2. The statement has been changed to read "low levels of acute toxicity."		Response acceptable.	N/A

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			control (*i.e.*, 67% of the samples show toxicity).				
			Please also update Section 6.3 as appropriate based on the response.			Please review Section 6.4 and ensure that the distinction between results of the 10- and 28-day toxicity test results are clear when summarizing "levels of toxicity". Language in Section 6.4.1 should be clarified.	Section 6.4.1 has been reviewed and toxicity terms have been clarified with respect to the specific endpoint being discussed and whether it is acute or chronic.
186	Appendix E, Table D-1a		Please indicate which TRVs were developed specifically for the NBSA BERA and distinguish between those for which no LPR TRVs were available and those developed because the LPR TRV was not habitat-appropriate (e.g., freshwater).	This information is provided in Table D-1.		This response will be evaluated following revisions to Appendix D based on supplemental comments.	The TRV tables (Table 6-18, Table 7-5, Table 7-11, Table 8-5, Table 9-3) have been updated to indicate which TRVs are from the LPR OU4 BERA and which were developed specifically for the NBSA BERA.
Additional Comments received 2-28-2020							
A-187	Appendix E, Table E-2-x (various)	N/A	N/A	N/A	N/A	Please revise incorrect exposure factor parameter terminology [should be DF sediment (incidental) and DF plant rather than "NBSA RI" and "BERA"].	Row headers in Appendix E tables have been revised.
A-188	Appendix C, Table C-15	N/A	N/A	N/A	N/A	Please add "Sediment EPC" to column header.	Appendix C Table C-15 is for fish eggs not sediment. No revisions were made in response to this comment.
A-189	Table C-17	N/A	N/A	N/A	N/A	Please correct the table as the Total PCB Dioxin TEQ should use the Niimi 1983 CV rather than the Russel et al. 1999, which appears twice.	Appendix C Table C-17 has been updated.
A-190	Table 9-2	N/A	N/A	N/A	N/A	The USEPA, 1999 OSWER document included in the reference list does not appear to be the appropriate reference in this table; please revise the table and reference list as necessary.	Reference has been updated.
A-191	Appendix C	N/A	N/A	N/A	N/A	In many cases, where the maximum (detected or undetected) concentration was selected as the basis for the EPC, the values in the "Selected EPC" column in these tables are incorrect, although it appears that the correct values were carried forward to support the risk calculations presented in Appendix E. Please revise as necessary.	The Appendix C "Selected EPC" column has been revised.

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A-192	Appendix C Table C-1; Table 4-9, Table 4-10. Need to reconcile	N/A	N/A	N/A	N/A	Sample numbers for the shoreline categories (NBSA-wide and individual assessment zones) do not appear to have been updated from the draft and are not consistent with the revised Table 4-9. Please revise this and dependent tables (e.g., muskrat risk calculations) as necessary.	See also Comments 50 and 53. Tables 4-9, 4-10, and C-1 were revised.
A-193	123; main text	N/A	N/A	N/A	N/A	The fish pathology study conducted during the fish tissue collection program to support the BERA is used as a LOE in the WOE integration. Although some pathologies were noted, the BERA argues that they are relatively minor and observed in low frequencies, and overall supports a conclusion that the fish community is not at risk in NBSA. The fact that many of the individual fish that were evaluated in the pathology study were migrants coming into the bay to spawn or forage bears on its relevance to understanding potential impacts associated with NBSA conditions and is an uncertainty that should be considered in evaluating this LOE. In contrast, the Bugel (2010) pathological study did detect reproductive impacts to resident killifish; these impacts are entirely consistent with a stressor-response profile for dioxins/furans and PCBs. Although the Bugel study is described in Section 7.7.1, only the RI/FS study was incorporated into the WOE integration process in Section 11. The LPR FFS TRV is 3 orders of magnitude lower than the NBSA value and although it is based on a conservative endpoint, behavioral effects such as those evaluated in the Couillard et al. (2011) study could directly impact predator avoidance and foraging success correlating with the standard survival and growth endpoints. Per EPA direction and consistent with the process used in the OU4 BERA, preliminary COCs should be based on any LOAEL HQ exceeding 1 - for foraging fish, COCs should include all organics COPECs included in Table	1. The Bugel et al. (2010) results have been acknowledged in Table 11-1a (WOE). 2. This comment has been resolved with the adoption of the LPR BERA TRVs in the NBSA BERA. See Appendix D and Section 7 for updated TRV information. 3. See responses to Comment #3 and #175.

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						7-20. In Table 7-20, the Bugel findings are consistent with the LPR FFS and not the NBSA tissue endpoint results and should be included.	
A-194		N/A	N/A	N/A	N/A	Please remove Tables 7-19, 8-10 and 9-7 which assign reliability scores to TRVs for preliminary COCs along with referencing text, as the approach is not supported by a strong historical framework and is subjective in nature. Factors discussed in Section 3.5.3 that may be important to consider during the refinement of toxicity thresholds in the FS should be identified for individual preliminary COCs but must be presented in an unbiased and critical fashion.	Reliability scoring tables have been removed.
A-195	67	N/A	N/A	N/A	N/A	Please review added text regarding variability, including rephrasing the ambiguous third sentence and checking the reported alpha and MDD values that appear to differ from the referenced table.	The typographical errors have been corrected. Specifically, the alpha = 0.05 and the confidence expressed in the footnote to Table A-2-1 (i.e., 95%) have been corrected. The MDD for 28-day survival is 33%, which has been corrected in the text. The third sentence has been deleted.
A-196	Table A-2-1	N/A	N/A	N/A	N/A	Please ensure that all stations that are significantly different from control based on the estimated MDDs are properly identified and the document revised as necessary.	Toxicity values that are less than the control value minus the MDD are now identified in Table A-2-1 and in Tables 6-4, A-5 and A-7. The text citing these tables has been revised to note this change.
A-197		N/A	N/A	N/A	N/A	The sensitivity analyses (see Comments # 135, 152, 153 and 170) that are presented in the Appendices provide valuable information on the impact of parameter estimation uncertainty on the risk estimates and this information should be carried through the BERA, included in the section summaries and identified as preliminary COCs. Information that may be useful for consideration in the FS can also be provided.	See responses to Comments 3 and 135.

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A-198		N/A	N/A	N/A	N/A	Please revise once comments on use of reliability scoring, uncertainties associated with site-specific datasets and TRV biases have been addressed. Table 1 (included with these back-check comments) provides an example integration of information for preliminary fish tissue COCs. Consistent with the Final OU4 BERA, this table includes all COPECs with LOAEL HQs equal to or are greater than 1 and summarizes important specific uncertainties for each. The file also includes additional tables/figures that support the specific uncertainty discussions. See tab "RTC #A-198 Table 1 02-28-2020.	Preliminary COC summary tables have been added to the WOE sections of Section 6 (Table 6-21), 7 (Table 7-19), 8 (Table 8-10), and 9 Table (9-7).
Supplemental Comments from USEPA Clarification Dated January 6, 2020							
187	Appendix D		N/A	N/A	A number of potential inconsistencies between the Windward 2017/2019 TRVs and those identified in the draft NBSA BERA were identified (initial review had focused on those indicated in the TRV tables as having been generated specifically for the NBSA BERA). Specifics issues are identified in the attached Excel file. Inconsistencies include referencing the 2017 LPR BERA but the TRVs are not consistent, use of the same TRVs but the 2017 LPR BERA is not referenced and finally, instances where different TRVs were selected in lieu of 17-mile BERA values that had been verified by EPA. In a majority of cases, the decision to develop de novo TRVs specifically for the NBSA BERA appears to be due to difference in ecological habitat conditions in the two OUs and the desirability of using receptors and test conditions appropriate for the estuarine conditions in the NBSA. However, there are a number of instances where the rationale is not clear. Please revise the information in Appendix D (toxicological profiles) and the main text as appropriate to address these apparent inconsistencies.	N/A	Appendix D and the NBSA BERA text and tables have been revised following adoption of LPR OU4 BERA TRVs.

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188	Appendix D		N/A	N/A	The supplemental TRV information provided by Carlie Thompson in an email (15 August 2019) included information presented in Appendix A of the 2017 17-mile LPR BERA. Review of this information determined that Windward had included toxicological data and identified TRVs (based on various selection criteria) in Appendix A for some analytes that were not 17-mile BERA COPECs and as a result, the literature sources were not verified by EPA as part of their review of this document. For the 17-mile BERA review, EPA did accept TRVs derived from standard agency compilations (e.g., Eco SSL documents, ERED database) without verifying the information in the primary literature sources ; however, there appears to be a number of TRVs that were directly drawn from primary literature sources that will need to be verified. Please provide reprints for the indicated endpoint/COPEC references.	N/A	The NBSA BERA adopted the TRVs derived for the LPR OU4 BERA. For COPECs that were not evaluated by the LPR OU4 BERA, TRVs were derived from the information in LPR OU4 BERA Appendix A and are discussed in detail in Appendix D. Requested references were sent to EPA on February 6, 2020.
189	General Comment		N/A	N/A	Per direction from EPA and consistent with the exposure parameter and TRV memorandum (Arcadis, 2017), TRVs developed to support the LPRSA 17-mile BERA (OU4; Windward, 2017/2019) were to be used in the NBSA BERA where available and deemed appropriate; the LPRSA FFS TRVs (USEPA, 2014) were required to be used as well. In preparing comments on the draft NBSA BERA, EPA focused on the values identified in the BERA TRV summary tables that were developed specifically to support the NBSA analysis (because the analytes were not COPECs for the OU4 BERA or and FFS). Following the process employed by EPA during its review of the OU4 BERA, EPA checked the references for this subset of NBSA BERA TRVs in order to confirm (verify) that the values were consistent with	N/A	The NBSA BERA adopted the TRVs derived for the LPR OU4 BERA. For COPECs that were not evaluated by the LPR OU4 BERA, TRVs were derived from the information in LPR OU4 BERA Appendix A and are discussed in detail in Appendix D. Requested references were sent to EPA on February 6, 2020.

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					information provided in the cited references. For a number of TRVs, EPA either did not have the references on hand or could not verify the TRV values, and requested that GSH provide additional information to support the verification process. GSH subsequently provided the requested information (Carlie Thompson, August 2019) and EPA confirmed that the NBSA TRVs were consistent with this supporting documentation. Since that initial literature verification effort, EPA became aware of several issues that had not been appreciated during the preparation of the initial comments and conducted a more thorough review of the TRVs, including a specific focus on Appendix D. While some errors in TRV values were identified during this process, the primary focus of these supplemental comments is to ensure that the rationale for using alternatives to the OU4 BERA TRVs are made explicit throughout the document. The general issues, as well as comments on specific BERA tables, are provided below. EPA determined that many of the NBSA TRVs were selected from toxicological information summarized in appendix tables provided in the OU4 BERA (Appendix A3). In both the draft final (Windward, 2017) and final (Windward, 2019) BERA documents, Windward summarized results of its review of the relevant toxicological literature and applied evaluation criteria to select specific studies recommended for the development of NOAEL and LOAEL TRVs. The Windward Appendix A3 tables presented superfluous toxicological data for many analytes that are often selected as COPECs at contaminated sediment sites, including information for analytes that were not COPECs for the		

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					OU4 BERA. During its review of that document, EPA only verified the information for the specific OU4 BERA COPECs and as a result, the information for other analytes that were used by GSH and its consultants to support development of the draft NBSA TRVs still needs to be verified by EPA. The affected TRVs are summarized in a table below and GSH is requested to provide the source information for the indicated studies that are not immediately available to EPA.		
190	General Comment	OU	N/A	N/A	Please update references to the final (Windward 2019) OU4 BERA and verify that the referenced information from the draft final (Windward 2017) is still current.	N/A	The reference to the final Windward 2019 OU4 LPRSA BERA was updated throughout the document.
191	General Comment		N/A	N/A	The introductory section of Appendix D (toxicity profiles and TRVs) describes the general approach for selecting TRVs and decisions regarding whether to use available OU4 TRVs or develop alternative values. Where OU4 values are available but alternative values were used in the Draft NBSA BERA, please provide the OU4 values (either based on individual studies or SSDs) for comparison and provide the specific rationale for selecting the alternative TRVs (which resulted in the inconsistencies between the two analyses). In a majority of cases, the decision to develop de novo TRVs specifically for the NBSA BERA was related to differences in ecological habitat conditions between the two OUs and the desirability of using receptors and test conditions appropriate for the estuarine conditions in the NBSA; however, the rationale is not always clear and should be made explicit throughout Appendix D.	N/A	Appendix D has been revised following EPA approval of the use of LPR OU4 BERA TRVs for the majority of endpoints/COCs in the NBSA BERA.

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192	General Comment		N/A	N/A	The introductory sections of Appendix D describe the general approach to selecting TRVs to support the NBSA BERA and it would be helpful to summarize the Windward approach, including acceptability criteria, that were used in the OU4 BERA. It is particularly critical that all deviations criteria be discussed and the rationale provided. Some of these inconsistencies include the use of freshwater species when estuarine data are available and the inconsistent use of TRVs developed using Species Sensitivity Distributions (SSDs) and chicken toxicological studies. It is recommended that the introductory discussion in Appendix D be revised to provide additional details on how TRV selection decisions were made, particularly how counterbalancing concerns were evaluated. Cases where TRVs based on single studies were selected in lieu of OU4 BERA SSDs, and the use of chicken data when information on wildlife species are available (e.g., bird diet nickel TRV), should be discussed in the appropriate Appendix D subsections and the rationale for the selected TRVs provided.	N/A	Appendix D has been revised following EPA approval of the use of LPR OU4 BERA TRVs for the majority of endpoints/COCs in the NBSA BERA.
193	General Comment		N/A	N/A	There are instances where the draft NBSA BERA used the same literature reference as the OU4 BERA, but different TRV values were derived. Please check the values used in the draft NBSA BERA and either revise the values or ensure that the reasons for the discrepancies are clearly presented.	N/A	TRVs used for the NBSA BERA have been updated.
194	General Comment		N/A	N/A	In the individual Appendix D TRV summary tables, please clarify the intended meaning of all numerals ("1" and "2," or "3") in the source note column. What does "TRV derived for the NBSA BERA" mean in cases where	N/A	Appendix D summary table source numbers have been revised.

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					the NBSA and OU4 BERAs (or FFS) are the same value?		
195	General Comment		N/A	N/A	Please update Appendix D (Toxicity Profiles) to explain discrepancies between the TRVs selected for NBSA and OU4, where both are cited as the sources. These discrepancies are primarily are due to decisions to apply extrapolation factors to estimate NOAEL TRVs based on reported LOAELs. Examples include the TCDD TRV for polychaetes and blue crabs based on the Ashley et al. (1996) study and the hexachlorobenzene TRV for Japanese Quail based on the Vos et al. 1971 (1971) study. The NBSA BERA variously applied or didn't apply extrapolation factors relative to the approach used in the 17-mile LPR analysis. The additional information will help resolve apparent inconsistencies between the two BERAs as well as providing readers with a better understanding of the study uncertainties.	N/A	TRVs used for the NBSA BERA have been updated and the text and tables in Appendix D have been revised.
196	General Comment		N/A	N/A	Appendix D does not include subsections for tributytin, cobalt, and vanadium, which are COPECs for the bird and mammal diet endpoints. Summary tables and supporting text for these additional COPECs should be prepared and added to Appendix D.	N/A	TBT, cobalt, and vanadium are not COPECs for the bird or mammal dietary evaluation. The bird and mammal dietary TRV tables were revised to remove these constituents.
197	General Comment		N/A	N/A	In some cases, it is not clear whether TRVs were drawn from EPA or agency TRV compilations (e.g., EcoSSL or USACHPPM documents) or the primary literature referenced. In addition to referencing use of the information in the OU4 BERA (Appendix A3) where appropriate as part of the TRV consistency requirement, secondary sources should be indicated in Appendix D (e.g., "as cited in …") and where values are referenced. The	N/A	The sources of the TRVs used in the NBSA BERA have been reviewed and revised.

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					EcoSSL documents were referenced in this fashion in the draft NBSA BERA; please verify that this was standard practice. EPA has determined that TRVs provided in appropriately peer-reviewed agency compilations do not need to be independently verified.		
198	Table 7-1		N/A	N/A	Please correct the reference for the Total PCB TRVs based on a study by Lerner.	N/A	The reference has been corrected.
199	Table 7-7		N/A	N/A	The table indicates that the selenium dietary NOAEL and LOAEL TRVs for fish receptors (0.106 and 0.192 mg/kg bw/day) were derived from a survival study in Chinook salmon (Hamilton et al., 1990) as summarized in Appendix A3-4 of the OU4 BERA (Windward 2019); however, Appendix D, Table D-59 cites a rainbow trout study by Knight et al. (2016) and discussion in 16.2.2.2 indicates that the LOAEL is based on Hamilton and NOAEL is based on Knight studies. Please reconcile this information. In addition, the discussion in Appendix D (Section 16.2.2.2) indicates, consistent with the approach used in Table 7-22 of the OU4 BERA (Windward 2019), that the selected LOAEL TRV was based on a geomean of three SSDs (0.11 mg/kg bw/day) and the NOAEL obtained by applying a 10-fold extrapolation factor to the LOAEL from a rainbow trout study (Knight et al., 2016). Please reconcile Table 7-7 and the information provided in Appendix D and the dependent tables and text. Also please reference the OU4 BERA, which summarized the individual studies and also derived the SSD.	N/A	The fish diet selenium TRV has been revised and relevant tables and text in Appendix D have been updated.
200	Table 7-10		N/A	N/A	Total PCBs NOAEL and LOAEL should be 0.0504 and 0.258 mg/kg, not 50.4 and 258 mg/kg, respectively. Also see Comment on Table D-7 regarding the NOAEL.	N/A	The fish egg Total PCB TRVs were revised to: NOAEL = 0.0258 mg/kg LOAEL = 0.258 mg/kg

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201	Table 8-2		N/A	N/A	Please reconcile the dieldrin TRV reference (Davison and Sell, 1974) with that indicated in Table D-16 (DeWitt, 1956); the latter appears correct.	N/A	DeWitt (1956) is the correct reference and has been revised.
202	Table 8-6		N/A	N/A	Please correct the Blus (1984) bird egg LOAEL value for Total DDx (2,4 & 4,4) – should be 3.0 mg/kg not 3.7 mg/kg – and revise risk calculations and text (including Appendix D) accordingly. Also, TRVs for mercury were developed to support the LPRSA FFS and should be included in the table and the risk analysis. The NOAEL and LOAEL TRVs are 0.011 and 0.11 mg/kg, respectively based on a reproductive endpoint in a study by Jackson (2011).	N/A	The Total DDx TRV was revised to use the TRV from the LPR OU4 BERA. The bird egg mercury LPR FFS TRV was added to the risk assessment.
203	Table 9-3		N/A	N/A	The mammal NOAEL and LOAEL TRVs for mercury used in the LPRSA FFS are 0.016 and 0.027 mg/kg-bw/day because a 10-fold subchronic/chronic uncertainty factor was applied to the Wobeser et al. (1976) study results. Please revise this and subsequent tables and text accordingly.	N/A	The FFS mercury TRV was revised and subsequent tables and text were revised.
204	Table D-1		N/A	N/A	Correct identification of missing COPECs not listed in Table 8-5. Please remove cadmium and Total PAH, which are not COPECs for bird egg tissue. In addition, please add tributyltin, cobalt, and vanadium as COPECs for bird and mammal diet endpoints (also see general comment).	N/A	Cadmium and Total PAH were removed from Table D-1. TBT, cobalt, and vanadium are not COPECs for the bird or mammal dietary evaluation. The bird and mammal dietary TRV tables were revised to remove these constituents.
205	Table D-2		N/A	N/A	(Benthic Invertebrate 2,3,7,8-TCDD TRVs). The source notes for the Cooper and Wintermyer (2009) study included a reference to the OU4 BERA but it was not located in Windward, 2019. Please correct as necessary.	N/A	The benthic invertebrate 2,3,7,8-TCDD TRVs have been revised.
206	Table D-4		N/A	N/A	(Bird 2,3,7,8-TCDD and TEQ TRVs). For the OU4 BERA bird egg TRVs, consistent with the text, please add the Nosek et al. (1992a) reference and Key Uncertainty (KU) "a" because the NOAEL is based on a single study (not a SSD).	N/A	The bird egg TRVs for 2,3,7,8-TCDD and TEQ have been revised to use the LPR OU4 BERA TRVs. The NOAEL was derived from the LOAEL using an extrapolation factor of 10.

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207	Table D-5		N/A	N/A	(Mammal 2,3,7,8-TCDD and TEQ TRVs). The Hochstein et al. (2001) NOAEL and LOAEL TRVs should be 2.6E-6 and 8.8E-6, not 2.6E-5 and 8.8E-5, respectively. Appendix D text and Table 9-3 values are correct.	N/A	The Table D-5 values have been updated.
208	Table D-6		N/A	N/A	(Benthic Invertebrate PCB TRVs). For the blue crab TRVs, please add Hansen et al. (1974) to the references, "1" to source notes and an "a" to the KU because the Hansen study was used to derive the NOAEL value rather than application of a 10-fold extrapolation factor to a SSD, as was done in Windward, 2019.	N/A	The benthic invertebrate TRVs for Total PCBs have been revised. The NOAEL was derived from the LOAEL using an extrapolation factor of 10.
209	Table D-7		N/A	N/A	(Fish PCB TRVs). Please see comment on Table 7-10. The NOAEL value in Table D-7 was actually identified as a LOEC in Windward, 2019 (low end of the range in Appendix A, Table A3-3) based on reduced fecundity in Hugla and Thome (1999). As noted in the OU4 BERA (Windward, 2019), there is uncertainty associated with the lower Hugla and Thome value so perhaps, an extrapolated NOAEL (e.g., 0.0258 mg/kg) as was done in Table 7-34 (Windward, 2019) might be a suitable alternative NOAEL value. Please review and revise throughout the document as necessary. Also, why do the Lerner whole body TRVs have a "1" source note?	N/A	The fish egg Total PCB TRVs were revised.
210	Table D-8		N/A	N/A	(Bird PCB TRVs). Total PCB TRV (0.7 and 1.3 mg/kg for NOAELs and LOAELs, respectively; Chapman [2003]) are available from the FFS and should be included in the table, discussed in Section 3.3.2.2, and incorporated in the risk analysis.	N/A	The Total PCBs TRV from the LPR FFS were added to the bird diet risk assessment.
211	Table D-9		N/A	N/A	(Mammal PCB TRVs). Per Comment #165 (draft comment matrix), please describe the Bursian et al. (2013) study's mink PCB TRVs used in the Hudson River 5 Year Review Report (EPA, 2019) in Section 3.4.2. These values do not need to be added to	N/A	Discussion of the Bursian et al. (2013) study was added to Section 3.4.3 of Appendix D.

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					Table D-9 but should be addressed in the evaluation of uncertainties for the mammal risk analysis.		
212	Table D-11		N/A	N/A	(Fish Total DDx TRVs). Total DDx TRVs (0.078 and 0.39 mg/kg for NOAELs and LOAELs, respectively; Beckvar et al., 2005) are available from the FFS and should be included in the table, discussed in Section 4.2.2 in Appendix D, and incorporated into the risk analysis.	N/A	The FFS TRVs for Total DDx in fish tissue have been added to the risk assessment.
213	Appendix D, Section 4.3.2.2.		N/A	N/A	Please include the Windward (2019) DDx bird egg SSD NOAEL and LOAEL values (0.41 and 4.1 mg/kg, respectively) for comparison with the SSD values derived, excluding the chicken study.	N/A	The Total DDx in bird egg TRV was revised.
214	Table D-13		N/A	N/A	(Mammal Total DDx TRVs). Please correct the LPR FFS LOAEL value (should be 4.0 not 0.4 mg/kg bw/day). Also, the OU4 BERA should be cited in the source note (Appendix A3-7) for the Ware & Good (1967) study.	N/A	The TRV value was revised and the LPR OU4 BERA was added as a reference in the source note.
215	Table D-15		N/A	N/A	(Fish Dieldrin TRVs). Please add the study reference for the LPRSA FFS values.	N/A	Both the NBSA and LPR FFS TRVs were derived from the same study (Shubat and Curtis 1986), which is cited in Table D-15.
215	Table D-16		N/A	N/A	(Bird Dieldrin TRVs). Please include Windward (2019) in the source notes for the bird diet TRVs, as this study was selected in Table A3-6 in Windward (2019). Also, for the bird egg NOAEL TRV, please add a KU note as the value (0.3 mg/kg) was derived using an extrapolation factor as mentioned in the Section 5.3.2.2 text.	N/A	Windward (2019) was added as a source and a KU note was added for the Genelly and Rudd (1956) reference.
217	Table D-18		N/A	N/A	(Benthic Invertebrate Total Chlordane TRVs). Please correct inconsistency in NOAEL value for chlordane between the Section 6.1.2 text and Table D-18 (0.17 mg/kg versus 0.71 mg/kg, respectively); if 0.17 mg/kg is correct then Table 6-18 and risk tables/text will need to be revised as well. The table values are consistent with Windward (2019, Table A3-1) so the	N/A	0.71 mg/kg is the correct value. The risk analysis was revised using this value and the text in Appendix D Section 6.1.2 was revised.

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					source note should be updated to reference the OU4 BERA as well.		
218	Appendix D, Section 6.3.2		N/A	N/A	should have some discussion about the chlordane bird egg COPEC and the inability to develop TRVs. Were any studies identified but not considered appropriate?	N/A	Additional discussion about the lack of total chlordane TRV for bird egg has been added to Section 6.3.2.
219	Table D-19		N/A	N/A	(Fish Total Chlordane TRVs). Please include the OU4 BERA (Windward, 2019) to the source note column.	N/A	Windward (2019) was added as a source.
220	Table D-22		N/A	N/A	(Benthic Invertebrate Hexachlorobenzene TRVs). Hexachlorobenzene was not a COPEC for invertebrate tissue in Windward, 2019; however, NOAEL and LOAEL TRVs (10.6 and 15.8 mg/kg, respectively) were developed in Appendix A3-1 and the NBSA LOAEL is consistent with the latter value. Please reference the OU4 BERA in the source note and clarify why the NOAEL value was not used or update the table (and risk calculations/text).	N/A	Windward (2019) was added as a source for the benthic invertebrate hexachlorobenzene TRV and the NOAEL was included in the revised risk assessment.
221	Table D-23		N/A	N/A	(Fish Hexachlorobenzene TRVs). Please include reference to OU4 BERA (Table A3-2) in source notes.	N/A	Windward (2019) was added as a source.
222	Table D-24		N/A	N/A	(Bird Hexachlorobenzene TRVs). The NOAEL and LOAEL may be derived from separate experiments as the food ingestion rates are different (Windward, 2019; Table A3-6). If this is the case, please clarify in Appendix D, Section 7.4.2. Also, this section should discuss the lack of derived TRVs for the bird egg endpoint. Was any information available and if so, why was it determined inappropriate for developing TRVs?	N/A	When the LOAEL FIR and BW in the Vos et al. (1971) study were used instead of the NOAEL FIR and BW from that study, the NOAEL TRV did not change. Since, the LOAEL FIR and BW work for both the NOAEL and LOAEL TRV calculation, they are assumed to be the ones used in the TRV calculation. This section also discusses the lack of available TRVs for bird egg.
223	Table D-25		N/A	N/A	(Mammal Hexachlorobenzene TRVs). Please add reference to the OU4 BERA to the source notes.	N/A	Reference to the LPR BERA was added to the source note.

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224	Table D-26		N/A	N/A	(Benthic Invertebrate Total PAH TRVs). The LPRSA FFS Total HPAH NOAEL and LOAELs TRVs are 0.066 and 0.66 mg/kg (Eertman et al. 1993), not 0.022 and 0.22 mg/kg; please revise throughout document as necessary. Also, the total PAH LOAEL based on the Rice el al. (2000) study was also selected in Windward (2019) and should be included in the source note.	N/A	The Total HMW PAH TRV has been revised. Total PAHs are no longer evaluated as a COPEC for benthic invertebrate tissue.
225	Table D-28		N/A	N/A	(Bird Total PAH TRVs). The LPRSA FFS HPAH NOAEL and LOAEL TRVs (0.048 and 0.48 mg/kg, respectively based on Hough et al., [1993]) should be added to the table, as HPAH is a COPEC for this receptor. Please update Appendix D, Section 8.3.2 text as well. Also please add reference to the OU4 BERA in the source notes for the total PAH TRV. Finally, some justification for selecting the Patton and Dieter (1980) study TRV should be provided, particularly since OU4 BERA Appendix A3-6 provides some alternative values that identified effect thresholds for birds at exposures lower than the Patton and Dieter study.	N/A	Total HMW PAH was added to Table D-28 and Appendix D Section 8.3.2 was updated. The TRV based on Patton and Dieter (1980) was selected by LPR OU4 BERA and there were no alternative values available. This study was the only available acceptable study in Appendix A3-1 Table 6 that exposed birds to a PAH mixture in the diet.
226	Table D-29		N/A	N/A	(Mammal Total PAH TRVs). According to USEPA EcoSSL document, the Navarro et al. (1991) study of naphthalene exposure effect on rat growth resulted in NOAEL/LOAEL of 50 and 150 mg/kg bw/day, respectively, and the Culp et al. (1998) study of BaP exposure to juvenile mice for 55 weeks resulted in NOAEL/LOAEL for growth endpoints of 3.09 and 12.4 mg/kg bw/day, respectively. Also, note that the NOAEL/LOAELs for the same 65-week study (Culp et al., 1998) of survival in juvenile mice were 0.615 and 3.07, respectively. This should be noted in the discussion and a rationale for not selecting TRVs based on the more sensitive survival endpoint provided. Please revise the information in the table, make references	N/A	The selected NBSA TRV for Total PAH is the same as the LPR FFS (HMW PAH) - the Culp et al. (1998) study with mouse survival as the endpoint. The only other HPAH study in Appendix A3-1 was for BaP with a LOAEL = 10 mg/kg (higher than the Culp et al. [1998]). No changes were made in response to this comment.

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					consistent with Table 9-4, and also provide the rationale for applying a 100x factor to the study LOAEL to estimate the total PAH LOAEL. Also, include a reference to the document from which the values were obtained, along with the primary reference (e.g., as cited in…). The Total PAH TRVs are referenced variously as Culp et al., 1998 (Table D-29) and USEPA, 2007c (Table 9-3).		
227	Table D-30		N/A	N/A	(Benthic Invertebrate Arsenic TRVs). Windward (2019) developed invertebrate NOAEL/LOAEL TRVs for arsenic (0.064 and 0.64 mg/kg, respectively in Table 6-21) based on a SSD. Please reference the OU4 BERA values and provide an explanation for why they were not selected.	N/A	The benthic invertebrate arsenic TRV was revised.
228	Table D-31		N/A	N/A	(Fish Arsenic TRVs). The Balzer et al. (1977) study was evaluated in Windward (2019) and was rejected as the basis for TRVs because of food refusal behavior noted (Table A3-4). Please discuss the basis for the fish diet NOAEL (0.52 mg/kg bw/day) in Section 9.2.2.2 and include the OU4 BERA reference in the source note column.	N/A	The food refusal in Blazer et al. (1997) is discussed in Section 9.2.2.2. Windward (2019) was added as a source.
229	Table D-34		N/A	N/A	(Benthic Invertebrate Cadmium TRVs). Windward (2019) developed invertebrate NOAEL/LOAEL TRVs for cadmium (0.024 and 0.24 mg/kg, respectively in Table 6-21) based on a SSD. Please reference the OU4 BERA values and provide an explanation for why the OU4 values were not selected.	N/A	The benthic invertebrate cadmium TRV was revised.
230	Table D-35		N/A	N/A	(Fish Cadmium TRVs). Please reference the OU4 BERA in the source notes column.	N/A	Reference to the LPR OU4 BERA (Windward 2019) was added to the source note.
231	Table D-37		N/A	N/A	(Mammal Cadmium TRVs). Windward (2019) developed mammal diet NOAEL/LOAEL TRVs for cadmium (3.5 and 13 mg/kg bw/day, respectively based on a study by Machemer and Lorke, 1981). Please reference the OU4 BERA values and provide a discussion	N/A	The mammal cadmium TRV was revised.

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					of why the OU4 values were not selected.		
232	Table D-38		N/A	N/A	(Benthic Invertebrate Chromium TRVs). Windward (2019) developed invertebrate NOAEL/LOAEL TRVs for chromium (1.5 and 3.5, respectively, based on an amphipod study by Norwood et al., 2008, see Table 6-21). Please reference the OU4 BERA values and provide an explanation for why the OU4 values were not selected.	N/A	The benthic invertebrate TRV for chromium was revised.
233	Table D-39		N/A	N/A	(Fish Chromium TRVs). The Walsh NOAEL fish diet TRV (0.92 mg/kg bw/day) is consistent with Windward (2019) Appendix A3-4; however, the chromium NOAEL in Table 7-22 is 0.19 mg/kg bw/day. Please confirm that 0.92 mg/kg bw/day is the correct value, otherwise revise the document as necessary.	N/A	0.19 mg/kg bw/day is the correct value and has been revised.
234	Table D-40		N/A	N/A	(Bird Chromium TRVs). Windward (2019) Appendix A Table A3-6 selected an unpublished study by Haseltine et al. - cited in Sample - as the basis for the recommended NOAEL/LOAEL TRVs (1 and 5 mg/kg bw/day). Please provide the rationale for selecting a chicken study over the selected OU4 BERA TRVs for a native species (black duck).	N/A	Additional discussion of the Haseltine et al. paper has been added to Section 11.3.2.
235	Table D-42		N/A	N/A	(Benthic Invertebrate Copper TRVs). Add reference to the LPRSA FFS as the source for the NOAEL and LOAEL TRVs (based on Absil et al., 1996).	N/A	The LPR FFS (USEPA 2014) was added as a source.
236	Table D-43		N/A	N/A	(Fish Copper TRVs). Windward recommended against selection of the Mount fish tissue study as a basis for developing TRVs and evaluated only the FFS TRVs (Windward, 2019); please summarize the concerns raised in the OU4 BERA and provide an explanation for selecting the Mount study.	N/A	Additional text on the Mount et al. (1994) study was added to Appendix D Section 12.2.2.1.
237	Table D-45		N/A	N/A	(Mammal Copper TRVs). Please reference the OU4 BERA NOAEL and LOAEL TRVs (18 and 26 mg/kg bw/day; Table A3-7) and explain how different TRVs were established using the same	N/A	The mammal TRV for copper has been revised.

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					Aulerich et al., 1982 study of reproductive effects in mink.		
240	Table D-46		N/A	N/A	(Benthic Invertebrate Lead TRVs). Please add the NOAEL and LOAEL TRVs for lead??? (0.52 and 2.6 mg/kg, respectively) from the OU4 FFS based on Borgmann and Norwood (1999) study. Also, Windward (2019) developed an invertebrate TRV for lead (NOAEL/LOAELs are 4 and 40, respectively, based on amphipod survival study by Spehar et al., [1978] - see Table 6-21). Please add discussion of the OU4 BERA TRVs to Appendix D, Section 9.1.2 and provide an explanation why the these were not selected.	N/A	The LPR FFS (USEPA 2014) TRVs from Bormann and Norwood (1999) were added to Table D-46.

The benthic invertebrate TRV for lead has been revised. |
| 241 | Table D-49 | | N/A | N/A | (Mammal Lead TRVs). Please briefly discuss the Azar et al. (1973) NOAEL/LOAEL TRVs (11 and 90 mg/kg bw/day, respectively, which were selected by Windward (2019) - see Appendix A3-7). | N/A | The mammal lead TRV has been revised |
| 242 | Table D-51 | | N/A | N/A | (Fish Methylmercury TRVs). SSD-based NOAEL and LOAEL TRV values for methylmercury` presented in the OU4 BERA (0.035 and 0.35 mg/kg, respectively in Table 7-6) should be discussed in Appendix D Section 14.2.2.1 and an explanation for selecting alternative values provided. In addition, Windward (2019) also summarized results of the Matta et al. (2001) study and selected TRVs (Appendix A Table A3-2) for methylmercury in fish tissue. While the LOAEL (0.47 mg/kg) is the same as presented in Table D-51, Windward identified a different NOAEL (0.2 mg/kg) and this discrepancy should be discussed. In addition, please add the Windward (2019) reference to the source notes for this study. | N/A | The fish methylmercury TRV has been updated. |

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243	Table D-52		N/A	N/A	(Bird Methylmercury TRVs). The KU for the bird egg TRV values is confusing as the LOAEL was based on the geomean of LOAELs reported in 4 studies, not a single study as indicated. Please address.	N/A	The KU notes have been revised.
244	Table D-53		N/A	N/A	(Mammal Methylmercury TRVs). The mammal diet NOAEL and LOAEL TRVs presented in the table are 10-fold higher than the values used in the FFS because the subchronic/chronic extrapolation factor was not applied to the results of the Wobeser et al. studies. Please include the FFS values as a separate set of TRVs that are carried throughout the analysis and remove the source note to the FFS for the non-adjusted values.	N/A	The mammal TRV for methylmercury has been revised.
245	Table D-54		N/A	N/A	(Benthic Invertebrate Nickel TRVs). Please revise to indicate that the Borgmann et al. (2001) study TRV is based on Hyalella (amphipod) rather than copepod survival. Also, Section 15.1.2 describes development of a NOAEL value (0.10 mg/kg), which is included in Table 6-18, so please revise the "ND" in Table D-54.	N/A	Table D-54 was revised.
246	Table D-56		N/A	N/A	(Mammal Nickel TRVs). Please discuss the selected Windward (2019) NOAEL/LOAEL TRVs (20/80 mg/kg bw/day, respectively, in Ambrose et al. 1976).	N/A	The mammal nickel TRV has been revised.
247	Table D-59		N/A	N/A	(Fish Selenium TRVs). This study was used to derive NOAEL and LOAEL TRVs (Table A3-2), so please add reference to Windward (2019). Also, please identify the NOAEL developed in the OU4 BERA (1.1 mg/kg bw/day) in Section 16.2.2.1 and explain why it was not used.	N/A	The fish selenium TRV was revised and the source note updated.
248	Table D-61		N/A	N/A	(Mammal Selenium TRVs). Note that a sentence is repeated in Section 16.4.2. Also please reference the selected LOAEL TRV (Windward, 2019; Appendix A3-7) and explain why alternative TRVs were selected. Finally, the EcoSSL	N/A	The repeat sentence was deleted. The mammal selenium TRV has been revised.

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					(USEPA, 2007c) document should be cited consistent with Table 9-3.		
249	Table D-63		N/A	N/A	(Fish Silver TRVs). Please include reference to Windward (2019) in source notes as Galvez and Wood (1999) included in Table A3-4.	N/A	Windward (2019) was added to the source notes.
250	Table D-66		N/A	N/A	(Benthic Invertebrate Zinc TRVs). Windward (2019) developed invertebrate NOAEL/LOAEL TRVs for zinc for several estuarine fauna including bivalve, crustaceans, and polychaetes (Table 6-21). Please summarize the OU4 BERA values and provide an explanation for why they were not selected.	N/A	The benthic invertebrate zinc TRV has been revised.
251	Table D-67		N/A	N/A	(Fish Zinc TRVs). In Section 18.2.2.1, please explain the concept of nutritional threshold and the basis for the value (403 mg/kg ww).	N/A	The discussion of the zinc nutritional threshold for fish has been revised Section 18.2.2.1.
252	Table D-68		N/A	N/A	(Bird Zinc TRVs). Please reference Windward (2019) and the bird dietary NOAEL and LOAEL TRVs (82 and 124 mg/kg bw/day; Table 8-11) based on a chicken growth study by Roberson and Schaible (1960).	N/A	The bird zinc TRV has been revised.
253	General Comment		N/A	N/A	Verification process. EPA reviewed primary literature used by Windward to develop TRVs for the OU4 BERA and verified all values developed specifically to support the Final 17-mile LPR BERA (Windward, 2019). For the NBSA BERA review, EPA requested literature source material for receptor/COPEC combinations unique to the NBSA, and following review, requested backup calculations for some TRVs that were not able to be immediately verified. GSH (memo from Carlie Thompson sent 15 August 2019) provided the requested documentation and the initial set of values were verified. However, during this review, EPA realized that many of the NBSA TRVs were derived from Appendix A3 in Windward (2017), which included TRVs for analytes that were not identified as COPECs for the	N/A	Arcadis provided requested papers to USEPA in February 2020.

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					OU4 BERA and which were thus not verified by EPA during the review of the LPRSA document.The following table summarizes studies that remain to be verified and those that EPA requests that GSH provide to expedite the review. Arcadis should indicate whether appropriate agency secondary sources were used (rather than TRVS being developed de novo from the primary literature) and the associated TRVs can be removed from the list of those requiring verification.		

Comment No.	USEPA Comment on April 2019 BERA draft.March 30, 2020	GSH Response
G-1	Please note that alternative SSD-based LOAEL TRVs for Total PCBs (invertebrate tissue) and 2,3,7,8-TCDD (fish tissue) were derived in the OU4 BERA and these should be included in the NBSA BERA and evaluated alongside the other TRVs in the uncertainty analysis. Risks (HQ>1) associated with these alternative TRVs should be carried through the analysis and considered when identifying preliminary COCs.	The alternative TRVs for Total DDX in benthic invertebrates and 2,3,7,8-TCDD in fish tissue are now included in the risk assessment.
G-2	The OU4 BERA generally applied a 0.1x factor to the 5th percentile estimates (LOAELs) of the selected distributional function from the OU4 SSD datasets to establish NOAELs. EPA acknowledges that alternative values based on empirical studies may also be appropriate (as GSH proposed for the NBSA BERA); however, please provide justification in the revised BERA that the selected studies are comparable to the OU4 SSD datasets with respect to receptor type, exposure pathways, and study endpoints. Please also consider and discuss any identified uncertainties in the body of the BERA as appropriate.	0.1x uncertainty factors have been applied to LOAEL TRVs to establish NOAEL TRVs where appropriate.
G-3	Please ensure that details on the derivation of all unique NBSA TRV values are provided in the revised NBSA BERA; refer to Appendix A of the OU4 BERA for type of information required and recommended format.	Additional details regarding the derivation of all unique NBSA TRVs is included in Appendix D.
S-1	Invertebrate tissue LOAEL TRV for Total PCBs. Whole body residues (wet weight basis) in brown shrimp for the 1 and 10 ug/L Aroclor 1016 treatment levels were 3.8 and 42 ug/g wet weight, respectively, and mortality levels were 8 and 43 percent (compared to 0 percent in control). The NOAEL from this study should be 3.8 mg/kg (not 0.4 mg/kg), and as this is higher than the SSD LOAEL, please consider adopting the OU4 NOAEL for this COPEC.	The invertebrate Total PCB NOAEL TRV has been updated to the following: LOAEL = 0.52 mg/kg NOAEL = 0.052 mg/kg
S-2	Invertebrate tissue LOAEL TRV for Total PAHs. The recommended value derived from Rice et al., 2000 is a worm prey concentration associated with a significant reduction in growth of juvenile English sole. The experimental sediment concentrations were selected for lack of toxicity to the test worm species based on previous testing and no adverse effects to invertebrates were identified. This study is potentially relevant to deriving a fish dietary TRV but is not appropriate for deriving a TRV for invertebrates. Instead it is recommended that GSH use the NOAEL/LOAEL tissue TRVs selected in the OU4 BERA (Table 6-20) based on Schuler et al., 2007 (8.1 and 22.2 mg/kg, respectively). This study was previously verified by USEPA and would be acceptable for use in the NBSA BERA.	Benthic invertebrate TRVs for LMW PAH and HMW PAH have been updated to the following: LMW PAH LOAEL = 111 mg/kg LMW PAH NOAEL = 11 mg/kg HMW PAH LOAEL = 22.2 mg/kg HMW PAH NOAEL = 8.1 mg/kg
S-3	Invertebrate tissue NOAEL TRV for cadmium. The proposed NOAEL value (0.12 ug/g) appears reasonable based on the data presented in Figures 2 and 3; however, please provide further details on how the specific value was derived (presumably predicted from regression results for the combined pathway dataset?) so that EPA can complete the verification step.	The benthic invertebrate TRVs have been updated to the following: LOAEL = 0.24 mg/kg NOAEL = 0.024 mg/kg
S-4	Fish tissue NOAEL TRV for Total PCBs. The OU4 BERA (Table 2 in Attachment A3) summarizes some information from the Hansen et al., 1971 study; however, the proposed value could not be verified. Please provide further details so that EPA can complete the verification step.	The fish tissue Total PCBs TRVs have been updated to the following: LOAEL = 3.8 mg/kg NOAEL = 0.38 mg/kg
S-5	Fish diet NOAEL TRV for chromium. Although the proposed value (0.92 mg/kgbw/day) is presented in the final OU4 BERA (Appendix A, Attachment A3, Table 4), it is not an appropriate basis for deriving a NOAEL TRV as it is based on dietary exposure assuming just consumption of sediment. The NBSA TRV should be consistent with the value selected in the OU4 BERA to estimate risk for this pathway as summarized in Table 7-22 (i.e., 0.19 mg/kgbw/day based on consumption of the alga, *Enteromorpha entestinalis*, as described in the Walsh et al., 1994 study). In addition, please verify whether the daily ingestion rate from the study is expressed on a dry weight basis as assumed in the above calculations or wet weight.	The fish diet chromium TRVs have been updated to the following: LOAEL = not derived NOAEL = 0.19 mg/kg bw/day

Comment No.	USEPA Comment on April 2019 BERA draft.March 30, 2020	GSH Response
S-6	Fish egg tissue LOAEL TRV for Total PCBs. 0.258 ug/g wet weight is the LOEC for hatching rate (% laid eggs), but a significant reduction in fecundity (eggs/kg) was reported at an egg concentration of 0.0504 ug/g wet weight, and this value should be selected as the LOEC instead. Therefore, the NOAEL should be 0.0248 ug/g wet weight, based on the control egg concentration.	The fish egg Total PCBs TRVs have been updated to the following: LOAEL = 0.258 mg/kg NOAEL = 0.0258 mg/kg
S-7	Avian diet NOAEL and LOAEL TRVs for dieldrin. The OU4 BERA (Table 6 in Attachment A3) summarizes some information from the Davison & Sell, 1974 toxicological study using mallard duck (not quail as cited in the revised BERA, please correct); however, the proposed value could not be verified. Please provide further details so that EPA can complete the verification step.	The incorrect reference was indicated in the TRV table. It should be DeWitt (1956) (quail mortality). The correct NOAEL TRV (0.08 mg/kg bw/day) and correct LOAEL TRV (0.12 mg/kg bw/day) from this study were in the table. These were the dieldrin TRVs selected by the LPRSA BERA in Appendix A3 Table 6. The reference has been corrected. The TRV values do not need to be changed.
S-9	Avian dietary LOAEL TRV for silver. The USEPA reference cites the Pesticide Ecotoxicity Database as the source of the toxicological data used in the development of the proposed dietary TRVs, and specifically a 14-day feeding study with juvenile mallards (LC50 >5620 ppm, NOEL 1800 ppm). From the available information it is unclear whether the database effect levels are reported as doses or dietary food concentrations. Also, 1,780 ppm appears to be a study NOAEL rather than LOAEL. As an alternative, EPA recommends that GSH consider using information in the EcoSSL document (USEPA, 2006); the mammal silver TRVs and several other NBSA TRVs are based on EcoSSL documents. One potential option would be LOAEL = 2.02 mg/kgbw-day (1/10 of lowest LOAEL - growth/reproduction for a 5 week exposure in juvenile turkeys with significant reduction in body weight). Alternatively, the LOAEL could be selected at 98.6 mg/kgbw-day for impacts to survival in a 3-week exposure to juvenile female mallards.	The bird diet silver TRVs have been updated to the following: LOAEL = 98.6 mg/kg bw/day NOAEL = 9.86 mg/kg bw/day
S-10	Mammal diet NOAEL TRV for Total DDx. EPA was able to verify the LOAEL TRV but not the proposed NOAEL value. In addition, Table 7 in OU4 BERA Appendix A, Attachment A3 indicated that a NOAEL was not available. Please provide further details so that EPA can complete the verification step.	The mammal diet Total DDx TRVs have been updated to the following: LOAEL = 1.3 mg/kg bw/day NOAEL = 0.13 mg/kg bw/day